

TAB 337

30(b)1 and 30(b)6 Deposition of Helton, Carolyn

October 16, 2009

Nashville, TN

1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE LITIGATION)
)
)
)
) MASTER CASE NO
) 01-12257-PBS

THIS DOCUMENT RELATES TO:)
United States of America ex rel.) SUBCATEGORY NO
Ven-A-Care of the Florida) 06-11337-PBS
Keys, Inc., et al. v. Boehringer)
Ingelheim Corporation, et al.,)
Civil Action No. 07-10248-PBS.)
)

30(b)(1) and 30(b)(6)

VIDEOTAPED DEPOSITION OF:

CAROLYN HELTON

Taken on Behalf of Roxane Laboratories

October 16, 2009

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<p style="text-align: right;">2</p> <p>1 APPEARANCES:</p> <p>2</p> <p>3 For the U.S. Department of Justice:</p> <p>4 JAMES J. FAUCI, ESQ.</p> <p>5 Assistant United States Attorney</p> <p>6 John Joseph Moakley Federal Courthouse</p> <p>7 1 Courthouse Way, Suite 9200</p> <p>8 Boston, Massachusetts 02210</p> <p>9 617.748.3298</p> <p>10 jeff.fauci@usdoj.gov</p> <p>11</p> <p>12 For Roxane Laboratories, Boehringer Ingelheim, and</p> <p>13 Related Companies:</p> <p>14 ERIC GORTNER, ESQ.</p> <p>15 Kirkland & Ellis</p> <p>16 300 North LaSalle Street</p> <p>17 Chicago, Illinois 60654</p> <p>18 312.862.2285</p> <p>19 ERIC.GORTNER@KIRKLAND.COM</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">4</p> <p>1 I N D E X</p> <p>2 WITNESS: CAROLYN HELTON</p> <p>3 INDEX OF EXAMINATIONS</p> <p>4 Page</p> <p>5 By Mr. Gortner 7</p> <p>6 By Mr. Fauci 127</p> <p>7 By Mr. Gortner 134</p> <p>8 INDEX OF EXHIBITS</p> <p>9 Page</p> <p>10 Exhibit Roxane 260 Declaration 9</p> <p>11 Exhibit Roxane 261 Red Book Excerpt 46</p> <p>12 Exhibit Roxane 262 Documents - Drug Pricing Boxes 70</p> <p>13 Exhibit Roxane 263 HCFA Transmittal 108</p> <p>14 Exhibit Roxane 264 Doxorubicin Hydro. Array 110</p> <p>15 Exhibit US 265 Search Database 130</p> <p>16 Exhibit US 266 Ipratropium Array 131</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>
<p style="text-align: right;">3</p> <p>1 APPEARANCES (Continued):</p> <p>2</p> <p>3 For the Dey Defendants:</p> <p>4 MARISA A. LORENZO, ESQ.</p> <p>5 Kelley Drye & Warren</p> <p>6 101 Park Avenue</p> <p>7 New York, New York 10178</p> <p>8 212.808.7697</p> <p>9 mlorenzo@kelleydrye.com</p> <p>10</p> <p>11 Also Present: Rudy Smith, Videographer</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">5</p> <p>1 The videotaped deposition of</p> <p>2 CAROLYN HELTON, taken on behalf of the Roxane</p> <p>3 Laboratories, on the 16th day of October, 2009, at</p> <p>4 9:02 a.m. in the offices of Walker, Tipps &</p> <p>5 Malone, 2300 One Nashville Place, 150 Fourth</p> <p>6 Avenue North, Nashville, Tennessee, for all</p> <p>7 purposes under the Federal Rules of Civil</p> <p>8 Procedure.</p> <p>9 The formalities as to notice,</p> <p>10 caption, certificate, et cetera, are waived. All</p> <p>11 objections, except as to the form of the</p> <p>12 questions, are reserved to the hearing.</p> <p>13 It is agreed that Elisabeth A.</p> <p>14 Miller, being a Notary Public and Court Reporter</p> <p>15 for the State of Tennessee, may swear the witness,</p> <p>16 and that the reading and signing of the completed</p> <p>17 deposition by the witness are reserved.</p> <p>18</p> <p>19</p> <p>20</p> <p>21 * * *</p> <p>22</p>

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<p style="text-align: right;">6</p> <p>1 PROCEEDINGS</p> <p>2 THE VIDEOGRAPHER: Here begins Volume</p> <p>3 1, Videotape No. 1 in the deposition of Carolyn</p> <p>4 Helton; In re: Pharmaceutical Industry Average</p> <p>5 Wholesale Price Litigation; in the United States</p> <p>6 District Court, District of Massachusetts. Case</p> <p>7 number is MDL1456. Today's date is October the</p> <p>8 15th [sic], 2009. Time on the video monitor is</p> <p>9 9:02 a.m.</p> <p>10 The video operator today is Rudy Smith.</p> <p>11 The video deposition is taking place at Walker,</p> <p>12 Tipps & Malone, Nashville, Tennessee.</p> <p>13 Counsel, please identify yourselves and</p> <p>14 state whom you represent.</p> <p>15 MR. GORTNER: Eric Gortner from</p> <p>16 Kirkland & Ellis representing Roxane Laboratories</p> <p>17 and Boehringer Ingelheim and related companies.</p> <p>18 MR. FAUCI: This is Jeff Fauci from the</p> <p>19 United States Attorney's Office, District of</p> <p>20 Massachusetts, representing the United States.</p> <p>21 THE VIDEOGRAPHER: Court reporter,</p> <p>22 would you please swear in the witness.</p>	<p style="text-align: right;">8</p> <p>1 some which may have been processed by the Cigna</p> <p>2 DMERC that I know you have worked for.</p> <p>3 I wanted to go over just a couple</p> <p>4 rules, which I know will be familiar to you from</p> <p>5 your prior deposition.</p> <p>6 The first is to make sure that you give</p> <p>7 verbal answers of either yes or no rather than</p> <p>8 nodding your head so that the court reporter can</p> <p>9 get a clear answer for you. Is that okay?</p> <p>10 A. That is okay.</p> <p>11 Q. And I'll try to remind you. Sometimes</p> <p>12 we all lapse into saying uh-huh or nodding our</p> <p>13 head, so I'll try to remind you of that as best I</p> <p>14 can.</p> <p>15 The other rule is to make sure that we</p> <p>16 try not to speak over each other. Sometimes you</p> <p>17 may think you know where my question is going or</p> <p>18 how it will end. But if possible, please wait</p> <p>19 for the question to end so that we can have a</p> <p>20 clear question and answer and not be talking over</p> <p>21 each other. Okay?</p> <p>22 A. Okay.</p>
<p style="text-align: right;">7</p> <p>1 MR. FAUCI: Marisa.</p> <p>2 MS. LORENZO: And Marisa Lorenzo from</p> <p>3 Kelley, Drye & Warren representing the Dey</p> <p>4 defendants.</p> <p>5 THE VIDEOGRAPHER: Reporter, would use</p> <p>6 please swear in the witness.</p> <p>7 CAROLYN HELTON, was called as a</p> <p>8 witness, and after having been first duly sworn,</p> <p>9 testified as follows:</p> <p>10 MR. GORTNER: Just for the record,</p> <p>11 although this deposition was noticed as a</p> <p>12 30(b)(1) deposition, counsel have agreed that the</p> <p>13 testimony will also serve as 30(b)(6) deposition</p> <p>14 testimony for the Cigna DMERC.</p> <p>15 EXAMINATION</p> <p>16 BY MR. GORTNER:</p> <p>17 Q. Good morning, Ms. Helton.</p> <p>18 A. Good morning.</p> <p>19 Q. As you know, my name is Eric Gortner,</p> <p>20 and I represent Roxane Laboratories and certain</p> <p>21 other defendants in this case which involves,</p> <p>22 among other issues, claims related to Medicare,</p>	<p style="text-align: right;">9</p> <p>1 Q. If you need a break at any time,</p> <p>2 please let me know. We're happy to take a break.</p> <p>3 A. Okay.</p> <p>4 Q. And if you don't understand a question</p> <p>5 that I'm asking, feel free to ask me to clarify</p> <p>6 it or repeat the question. I'm happy to do so.</p> <p>7 A. Okay.</p> <p>8 (Marked Exhibit Roxane 260.)</p> <p>9 BY MR. GORTNER:</p> <p>10 Q. I'm going to hand you what we have</p> <p>11 marked as Roxane Exhibit 260. And this is the</p> <p>12 declaration that you submitted in this case. And</p> <p>13 you recognize this document, don't you?</p> <p>14 A. Yes.</p> <p>15 Q. Could you explain generally how you</p> <p>16 came to sign that document and how you were</p> <p>17 approached about preparing such a document?</p> <p>18 A. The declaration, I was approached by</p> <p>19 the U.S. Attorney's Office that additional</p> <p>20 information was needed concerning certain</p> <p>21 aspects, so I was asked to review certain data</p> <p>22 and then try to put together my best recollection</p>

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<p style="text-align: right;">10</p> <p>1 and -- of what the events were.</p> <p>2 Q. Do you recall what aspects you were</p> <p>3 asked to look into?</p> <p>4 A. The aspects for the declaration was</p> <p>5 looking at how the prices change if you change</p> <p>6 the average wholesale pricing within your arrays.</p> <p>7 Q. Were you asked to look into the issue</p> <p>8 of how Cigna classified generic drugs versus</p> <p>9 brand drugs?</p> <p>10 A. On this particular declaration, I do</p> <p>11 not believe so. Let me --</p> <p>12 Q. Let me try --</p> <p>13 A. Yes.</p> <p>14 Q. Excuse me?</p> <p>15 A. I'm sorry.</p> <p>16 Q. That's okay.</p> <p>17 A. Actually, yes. There was a question</p> <p>18 that came up as to how we did look at brand</p> <p>19 names, so, yes, I did respond on that.</p> <p>20 Q. Okay. And are you looking at Page 13</p> <p>21 and 14 of your declaration? Is that the section?</p> <p>22 A. Yes.</p>	<p style="text-align: right;">12</p> <p>1 Q. And my question is, were you provided</p> <p>2 a particular program memoranda or a citation to</p> <p>3 that by counsel, or did you go back and find</p> <p>4 program memoranda on your own?</p> <p>5 MR. FAUCI: Object to the form.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. You can -- I'm sorry. Let me clarify</p> <p>8 one -- one issue that might come up in a</p> <p>9 deposition is there will be times I will ask</p> <p>10 questions that counsel for the Department of</p> <p>11 Justice may object and will object to the form of</p> <p>12 the question. But unless counsel instructs you</p> <p>13 not to answer the question, you'll still go ahead</p> <p>14 and answer the question anyway.</p> <p>15 This is one of those instances.</p> <p>16 A. Originally we were asked to explain</p> <p>17 how we did the pricing and then if we had a basis</p> <p>18 for it. We -- I believe that I sent -- or Barbara</p> <p>19 Douglas had provided that CMS transmittal in the</p> <p>20 first information. So then it was sent back to</p> <p>21 me, Is this the one you're referring to.</p> <p>22 Q. Okay. And when you say the first</p>
<p style="text-align: right;">11</p> <p>1 Q. What documents -- well, let me take a</p> <p>2 step back. Were you provided any documents from</p> <p>3 counsel to review?</p> <p>4 A. I was provided documents, one from the</p> <p>5 CMS, which we had already provided based on --</p> <p>6 from -- from CMS's instructions, so that's what</p> <p>7 we went back and looked at just to make sure that</p> <p>8 that was how we were basing it, which is what we</p> <p>9 were.</p> <p>10 We had already given that information</p> <p>11 in the -- when we provided the details.</p> <p>12 Q. What documents are you referring to?</p> <p>13 A. CMS gives instructions to the carriers</p> <p>14 on how to handle the drug pricing in determining</p> <p>15 the average wholesale pricing, so there was</p> <p>16 instructions there on how to make a determination</p> <p>17 between a brand name and a generic name.</p> <p>18 Q. Okay. Are you referring to -- to</p> <p>19 what's sometimes called a CMS or HCFA program</p> <p>20 memoranda? Is that the type of document that</p> <p>21 you're referring to?</p> <p>22 A. Yes.</p>	<p style="text-align: right;">13</p> <p>1 information, just so we're on the same page, are</p> <p>2 you referring to the -- the documents that Cigna</p> <p>3 had produced at earlier time points in the</p> <p>4 process of this litigation?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. So there was a program</p> <p>7 memoranda in -- in that initial production that</p> <p>8 you made reference to and then counsel asked you</p> <p>9 whether that was, in fact, the particular one</p> <p>10 that you were referring to; is that right?</p> <p>11 A. I believe that is the case.</p> <p>12 Q. And were there any other documents</p> <p>13 that were provided to you in the course of</p> <p>14 preparing your declaration with respect to this</p> <p>15 issue of generic versus brand classification?</p> <p>16 A. I was asked to take a look at some</p> <p>17 other spreadsheets that -- that were sent to me</p> <p>18 to confirm if I could tell from that spreadsheet</p> <p>19 how it was handled whether it was handled as a</p> <p>20 brand or a generic.</p> <p>21 Q. When you say a spreadsheet, are you</p> <p>22 referring to a spreadsheet with respect to how</p>

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<p style="text-align: right;">14</p> <p>1 Cigna classified drugs? Sometimes we call them 2 arrays in this litigation. 3 A. It may have been Cigna but not Cigna 4 DMERC, so -- 5 Q. Okay. Maybe it was the Part B of 6 Cigna? 7 A. Yes. 8 Q. I see. Okay. And I think -- we'll 9 get to those -- I think we'll get to those 10 documents a little bit later on today. And if we 11 do, let's make sure we're talking about the same 12 -- the same document. Okay? 13 A. (Witness nodded head.) 14 Q. Now, in the course of preparing your 15 declaration with respect to the issue of 16 classifying generics versus brands, did you 17 review any other documents aside from these 18 arrays we're talking about and the program 19 memoranda that you referred to? 20 A. I don't quite understand that. 21 Q. My question is, are there any other 22 documents that you reviewed to refresh your</p>	<p style="text-align: right;">16</p> <p>1 BY MR. GORTNER: 2 Q. By current version you mean this 2009? 3 A. I do. 4 Q. Okay. Is Cigna currently using the -- 5 the CD-ROM version of the Red Book, or is it 6 using an Internet based version of the Red Book? 7 A. We are using the CD. 8 Q. Okay. Did you look at any annual Red 9 Books printed -- the printed annual Red Book? 10 A. I did not have the copy of the annual 11 specifically that -- when the conversation was 12 going on for that year, so I may have looked at 13 pages that were -- but I don't -- I didn't have 14 the actual physical annual when the conversation 15 -- for the year that we were discussing. 16 Q. Now, in terms of the monthly Red 17 Books, what time frame did you look at? In other 18 words, what -- what years were these Red Books 19 from? 20 A. For this one, I just looked at a 21 couple of ones. I went back to 1993 and '4 -- 22 I'm sorry, I didn't have '3. I went to '94,</p>
<p style="text-align: right;">15</p> <p>1 recollection or understand how it was that Cigna 2 classified brands versus generics, other than the 3 documents we've just talked about? 4 A. We looked at some of the Red Book. 5 Q. And when you mean Red Book, are you 6 referring to the Red Book CD-ROMs or the -- the 7 hard copy printed versions? 8 A. Both. 9 Q. Both? Okay. 10 So tell -- just explain to me in more 11 detail what Red Books you looked at, which 12 versions and if you can recall the years as well. 13 MR. FAUCI: I would just counsel the 14 witness not to reveal any communications that she 15 had with any DOJ attorneys or her own attorneys 16 at Cigna regarding the transmittal of any legal 17 advice. It's fine to answer the question with 18 that in mind. 19 THE WITNESS: I looked at the hard copy 20 old monthly Red Books and how they were 21 formatted, and then I looked at current version 22 Red Book CD.</p>	<p style="text-align: right;">17</p> <p>1 which was the oldest one I had. 2 Q. In preparing your declaration, did you 3 have any conversations or any correspondence with 4 any other DMERC representatives? 5 A. No. 6 Q. Did you have any conversations or 7 correspondence with any individuals that worked 8 at Cigna relating to the classification of 9 generics versus brands? 10 A. I did, but not from a standpoint of 11 asking that person but more of a standpoint of 12 that person is my backup, and we have to train on 13 it just in the event that I couldn't come, if 14 something happened to me. 15 Q. I'm not sure I understand that answer. 16 Can you explain that a little bit more -- 17 A. Okay. 18 Q. -- in terms of -- maybe it would be 19 helpful to know the nature of the conversation 20 that you had with this individual. 21 A. For Cigna, we try to make it where we 22 have dual backups so that some person can always</p>

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<p style="text-align: right;">18</p> <p>1 fill in for you in the event -- I'm sorry, if 2 something happens to you, you're deceased or 3 whatever. So the information is -- this person 4 is being trained as my backup, so we discuss how 5 drugs were previously priced, how drugs are 6 currently priced. So it's in the context of the 7 old pricing versus the new pricing and training 8 her as a backup. 9 Q. What is this person's name? 10 A. Amber. 11 Q. And how long has Amber been your 12 backup? 13 A. She's been training as my backup for 14 about six months. I think it's about six months. 15 Q. Okay. So Amber wasn't involved in the 16 actual classification of the drugs that we're 17 going to be talking about, and in particular 18 there's a drug called Ipratropium 19 Bromide-Novaplast that was in the Cigna arrays 20 roughly from 2001 up until 2004. 21 I take it Amber wasn't involved in that 22 process of classifying that drug in the Cigna</p>	<p style="text-align: right;">20</p> <p>1 Cigna arrays, who would have been the person that 2 would have made the initial determination of 3 classifying the product as either a generic or a 4 brand? 5 A. For the DME, that would be me. 6 Q. So you were the actual person that was 7 looking at the -- the Red Book CD or the monthly 8 update or whatever medium of Red Book you were 9 looking at, looking at the name and how it was 10 listed and making that determination of how these 11 products should be classified in terms of 12 generics versus brands; is that right? 13 A. That's right. 14 Q. Now, when you were preparing your 15 declaration, did you have a specific recollection 16 of that particular Ipratropium Bromide-Novaplast 17 product? 18 A. No, I did not. 19 Q. Okay. So at the time you were asked 20 to prepare your declaration, there was a 21 situation where you remembered, Oh, I recall 22 Ipratropium Bromide-Novaplast, and these are the</p>
<p style="text-align: right;">19</p> <p>1 arrays; is that right? 2 A. Correct, she was not with the company 3 at that time. 4 Q. So she wasn't able to provide you any 5 information, was she, about how that particular 6 drug, the Novaplast drug, was categorized by 7 Cigna? 8 A. No. The conversation was strictly 9 from my end giving her information. 10 Q. And what was the information you were 11 giving her just generally speaking? 12 A. Just generally going over the old 13 pricing standards and the classifications, using 14 the CMS instructions; and under the new pricing, 15 how we handle those and the exceptions based on 16 CMS. 17 It's sort of like she's learning the 18 whole process. She has to know the old process; 19 she has to know the current process. 20 Q. Now, during the time period of 2001 to 21 2004, and in particular the time period when the 22 Novaplast Ipratropium Bromide was put into the</p>	<p style="text-align: right;">21</p> <p>1 reasons specifically why I put this particular 2 product as a brand versus a generic? 3 A. That is correct. 4 Q. So is what happened in a general sense 5 that you then went back to the arrays and went to 6 the program memoranda and attempted to 7 reconstruct how it was that this product was 8 classified as a brand versus a generic? Was that 9 generally the process that you did? 10 MR. FAUCI: Object to the form. 11 THE WITNESS: That is correct. 12 BY MR. GORTNER: 13 Q. And at any point in the course of 14 reviewing documents or arrays, did you obtain a 15 specific recollection of -- of how you actually 16 were doing it or the decision process that you 17 engaged in for the Ipratropium Bromide-Novaplast 18 product? 19 A. For me, the Novaplast still doesn't 20 stand out. The process is in place for me and 21 applies across for, so I don't see a 22 differentiation between the Novaplast and the</p>

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<p style="text-align: right;">22</p> <p>1 process.</p> <p>2 Q. Okay. So you -- you -- is it fair to</p> <p>3 say that you recall the process and you're</p> <p>4 assuming that the process was followed with</p> <p>5 respect to Ipratropium Bromide-Novaplus?</p> <p>6 MR. FAUCI: Object to the form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. GORTNER:</p> <p>9 Q. Aside from Amber, there was no one</p> <p>10 else that you have spoken with with respect to</p> <p>11 the classification of the Novaplus product?</p> <p>12 A. That is correct.</p> <p>13 Q. Were there different drafts of this</p> <p>14 declaration, or was this the only single product</p> <p>15 that you reviewed and signed?</p> <p>16 MR. FAUCI: Same instruction I gave</p> <p>17 earlier, but answer the question to the best of</p> <p>18 your ability.</p> <p>19 THE WITNESS: There were different</p> <p>20 drafts.</p> <p>21 BY MR. GORTNER:</p> <p>22 Q. Do you know what happened to those</p>	<p style="text-align: right;">24</p> <p>1 a writable one?</p> <p>2 A. Yes.</p> <p>3 Q. Did you keep the earlier versions of</p> <p>4 the -- of the declaration as PDFs on your</p> <p>5 computer?</p> <p>6 A. I don't know for sure. Some of them</p> <p>7 may still be there, but I don't know.</p> <p>8 MR. GORTNER: Jeff, I'll request that</p> <p>9 those drafts get produced to us.</p> <p>10 MR. FAUCI: I'll just state for the</p> <p>11 record that we will not be producing those. I</p> <p>12 feel I'm letting this go quite far afield. We --</p> <p>13 we'll think about it after, but my -- I'll be</p> <p>14 surprised if we produce those.</p> <p>15 MR. GORTNER: Okay. Well, we'll take</p> <p>16 that up at a different juncture.</p> <p>17 MR. FAUCI: Sure.</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. Okay. And so there were some</p> <p>20 different versions. Do you recall whether the</p> <p>21 versions differed with respect to the -- the</p> <p>22 issue of how you classified generics versus</p>
<p style="text-align: right;">23</p> <p>1 drafts?</p> <p>2 A. I quite honestly do not know. I mean,</p> <p>3 I think we combined them, but I can't say for</p> <p>4 sure that everything in every draft is in this</p> <p>5 one.</p> <p>6 Q. How were they conveyed to you? Was it</p> <p>7 sent to you as a Word document in an e-mail, for</p> <p>8 instance?</p> <p>9 A. I'm not sure that it was a Word</p> <p>10 document. It might have been a PDF document.</p> <p>11 Q. Okay. So sent as a PDF?</p> <p>12 A. Right.</p> <p>13 Q. And then what happened? You would</p> <p>14 open it up and print the document?</p> <p>15 A. I didn't usually print the document. I</p> <p>16 would read the document, make my changes, send</p> <p>17 the document back.</p> <p>18 Q. How would you make your changes on a</p> <p>19 PDF document?</p> <p>20 A. Save it as a PDF on my system, open it</p> <p>21 with a form of PDF, save it as a different PDF.</p> <p>22 Q. As a PDF that you can make changes to,</p>	<p style="text-align: right;">25</p> <p>1 brands?</p> <p>2 A. No.</p> <p>3 Q. So the changes would have been to</p> <p>4 other -- other issues?</p> <p>5 A. Yes.</p> <p>6 Q. What issues do you recall changed in</p> <p>7 the different drafts?</p> <p>8 MR. FAUCI: I'll caution the witness</p> <p>9 again not to reveal any communications with DOJ</p> <p>10 counsel or her own counsel that touch on legal</p> <p>11 advice or other legal issues in the drafting of</p> <p>12 the affidavit, but answer the question to the</p> <p>13 best of your ability.</p> <p>14 BY MR. GORTNER:</p> <p>15 Q. Ms. Helton, feel free to go through</p> <p>16 the declaration and take a look to see what</p> <p>17 sections you recall are different than this final</p> <p>18 version of -- was it a single earlier draft, or</p> <p>19 were there multiple drafts?</p> <p>20 A. I believe that there were drafts for</p> <p>21 two different possible cases or approaches.</p> <p>22 Q. What one might be for -- for a case</p>

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<p style="text-align: right;">26</p> <p>1 involving Roxane and one for Dey? Do you know 2 that?</p> <p>3 A. I'm not exactly sure on that.</p> <p>4 MR. FAUCI: I'll also object that I 5 believe Ms. Helton testified that there were no 6 changes to do with the classification of Novaplus 7 areas dealing with Paragraphs 17 to 31 of her 8 declaration. That's the -- other than the Zenith 9 Goldline issue, that is the limit of this 10 deposition.</p> <p>11 So I'll just object to the extent the 12 question is asking about areas beyond those two 13 topics.</p> <p>14 THE WITNESS: Do I --</p> <p>15 MR. FAUCI: I don't know if there's a 16 question pending or not.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. There is a question pending. It was, 19 after reviewing the declaration whether you can 20 recall what issues received changes between the 21 final declaration and the earlier draft.</p> <p>22 A. Looking at it, I'm thinking that the</p>	<p style="text-align: right;">28</p> <p>1 Q. You didn't look at what any other 2 DMERCs had -- representatives had testified about 3 the way they priced or classified drugs?</p> <p>4 A. No.</p> <p>5 Q. And have you ever spoken to any other 6 DMERC representative with respect to how they go 7 about classifying generics versus brand drugs?</p> <p>8 MR. FAUCI: In general or related to --</p> <p>9 MR. GORTNER: In general.</p> <p>10 THE WITNESS: In general, yes.</p> <p>11 BY MR. GORTNER:</p> <p>12 Q. And do you have a specific 13 recollection of -- of a conversation with a 14 particular person?</p> <p>15 A. In the past, the DMERCs worked 16 together to do the drug pricing, so there were 17 quarterly calls between the DMERCs to go over the 18 arrays that they had, and we would work together 19 if we had any discrepancies to try to find those 20 out. We also worked together to develop sort of 21 the same pricing.</p> <p>22 Q. When was the time frame those</p>
<p style="text-align: right;">27</p> <p>1 changes were for the albuterol, that there may 2 have been some charts.</p> <p>3 Q. What page in -- in particular are you 4 referring to?</p> <p>5 A. 15.</p> <p>6 Q. Okay. There may have been some charts 7 related to the albuterol sulfate heading on Page 8 15?</p> <p>9 A. But I quite honestly am not sure at 10 this point. I was thinking that there were some 11 charts that we removed because they got too 12 involved.</p> <p>13 Q. Anything else?</p> <p>14 A. (Witness shook head.)</p> <p>15 Q. You have to say no?</p> <p>16 A. I do not think so, sorry.</p> <p>17 Q. That's okay. I'll remind you of the 18 head nods. We all forget from time to time.</p> <p>19 In the course of preparing your 20 declaration, did you review any witnesses' 21 testimony?</p> <p>22 A. No.</p>	<p style="text-align: right;">29</p> <p>1 quarterly calls occurred?</p> <p>2 A. I believe for this it would have been 3 from 1999 to 2003. You're going through 2003, 4 correct?</p> <p>5 Q. Right.</p> <p>6 And you mean through -- it would have 7 gone through 2003?</p> <p>8 A. Correct.</p> <p>9 Q. Did they continue after 2003?</p> <p>10 A. Yes.</p> <p>11 Q. Up until what point?</p> <p>12 A. Cigna transacted out of the DMERC 13 in September of 2006, so up until that time, I 14 can say that they were still going on.</p> <p>15 Q. And these quarterly -- these quarterly 16 calls would have a representative from Cigna on 17 the call and someone from Palmetto if that was 18 the operative DMERC at the time and DMERC-A and 19 Administar; is that right?</p> <p>20 MR. FAUCI: Objection to form.</p> <p>21 THE WITNESS: Most of the calls would 22 have representatives from all four DMERCs.</p>

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<p style="text-align: right;">30</p> <p>1 BY MR. GORTNER:</p> <p>2 Q. Were you the Cigna representative that</p> <p>3 was on most of these calls?</p> <p>4 A. Most of the calls, yes.</p> <p>5 Q. And the purpose of these calls, as you</p> <p>6 stated, were -- was to coordinate your pricing</p> <p>7 arrays; is that right?</p> <p>8 A. To coordinate the fees that we</p> <p>9 developed.</p> <p>10 Q. Was this part of what's been called</p> <p>11 the Uniform Drug Pricing Project? Is that a name</p> <p>12 you're familiar with?</p> <p>13 A. I have heard the name. I would not</p> <p>14 think that this came in under that, but I'm not</p> <p>15 really sure. It was CMS instructions that the</p> <p>16 DMERCs work together. I don't know if that was</p> <p>17 based on Uniform or not.</p> <p>18 Q. Did you have an understanding as to</p> <p>19 why CMS was instructing the DMERCs to work</p> <p>20 together?</p> <p>21 A. So that we would all have similar</p> <p>22 pricing.</p>	<p style="text-align: right;">32</p> <p>1 calls. We would go through the codes and</p> <p>2 indicate what we had -- the fee. Anywhere we had</p> <p>3 differences, we would discuss the differences.</p> <p>4 BY MR. GORTNER:</p> <p>5 Q. With respect to ipratropium bromide,</p> <p>6 for example, would the call basically encompass</p> <p>7 all four DMERCs saying, We have established</p> <p>8 \$3.34, for instance, per milligram for</p> <p>9 ipratropium bromide, and if all of you had</p> <p>10 established that same amount, you'd move on to</p> <p>11 another J-code? Is that how that worked?</p> <p>12 A. That is correct.</p> <p>13 Q. So it wasn't a circumstance where you</p> <p>14 were actually reading to each other the</p> <p>15 particular drugs that you had in the array or the</p> <p>16 classifications of whether they were generics or</p> <p>17 brands; is that right?</p> <p>18 A. That's right.</p> <p>19 Q. And the reason you wouldn't do that is</p> <p>20 because as long as you had established the same</p> <p>21 fee there was uniformity among the DMERCs?</p> <p>22 A. Correct.</p>
<p style="text-align: right;">31</p> <p>1 Q. And what you mean by similar pricing</p> <p>2 is to make sure that the -- the fee payment that</p> <p>3 was established by each DMERC for, say,</p> <p>4 ipratropium bromide or a particular J-code would</p> <p>5 be uniform, all four DMERCs would be paying the</p> <p>6 same amount for each of those claims under that</p> <p>7 J-code?</p> <p>8 A. Correct.</p> <p>9 Q. And what was the nature of the</p> <p>10 discussions? Can you -- can you give me a flavor</p> <p>11 in terms of how you would have these phone calls</p> <p>12 to coordinate your arrays?</p> <p>13 MR. FAUCI: Objection to the form.</p> <p>14 THE WITNESS: Generally when we</p> <p>15 received -- each quarter we would have to do the</p> <p>16 pricing. So before each quarter, the DMERCs</p> <p>17 would set up a conference call between each other</p> <p>18 to discuss it. We had previously established</p> <p>19 which drug codes were routinely processed under</p> <p>20 the DMERCs, which had a coverage benefit.</p> <p>21 Each of the carriers would develop the</p> <p>22 fees using the regulations and bring those to the</p>	<p style="text-align: right;">33</p> <p>1 MR. FAUCI: Object to the form.</p> <p>2 BY MR. GORTNER:</p> <p>3 Q. At any point, was there a discussion</p> <p>4 about the particular drugs that were listed in</p> <p>5 the arrays for payments on ipratropium bromide?</p> <p>6 A. I do not recall one for . . .</p> <p>7 Q. Based on your recollection of the</p> <p>8 nature of these quarterly teleconferences, would</p> <p>9 you expect that conversation to have occurred</p> <p>10 between the DMERCs if you were all setting the</p> <p>11 same fee payment for ipratropium bromide during</p> <p>12 this time?</p> <p>13 A. I would not.</p> <p>14 Q. At any point during your -- your work</p> <p>15 at Cigna from 2001 through 2004, did you examine</p> <p>16 the ipratropium arrays for the other DMERCs?</p> <p>17 A. Actually look at their arrays?</p> <p>18 Q. That's correct.</p> <p>19 A. I don't recall doing it. I don't see</p> <p>20 a need where they would send it to me. However,</p> <p>21 as new people come in, they sometimes ask for</p> <p>22 help. So I can't say that I didn't absolutely,</p>

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<p style="text-align: right;">34</p> <p>1 but I do not recall it.</p> <p>2 Q. And was there an attempt during the</p> <p>3 time of 2001 to 2004 to try to get coordination</p> <p>4 between the four DMERCs to make sure that they</p> <p>5 were classifying drugs consistently as either</p> <p>6 generic or a brand across the DMERCs?</p> <p>7 A. My assumption is that we were all</p> <p>8 classifying them based on instructions, so, no. I</p> <p>9 mean --</p> <p>10 Q. Well, is the answer to the question,</p> <p>11 no, there wasn't a -- an attempt to coordinate</p> <p>12 among the four DMERCs to make sure they were</p> <p>13 classifying the drugs consistently as generics or</p> <p>14 brands?</p> <p>15 A. I don't believe that there was</p> <p>16 anything about generics and brands.</p> <p>17 Q. The focus was on making sure that the</p> <p>18 actual fee payment came out the same for the four</p> <p>19 DMERCs?</p> <p>20 A. Yes.</p> <p>21 Q. Now, as a Cigna representative, did</p> <p>22 you have any concerns whether the DMERCs were</p>	<p style="text-align: right;">36</p> <p>1 100, Ms. Helton, and it's a document entitled</p> <p>2 Medicare Pricing, Drug Pricing Procedure. Would</p> <p>3 you take a quick look at the document and tell me</p> <p>4 if you recognize it?</p> <p>5 A. I have seen the document.</p> <p>6 Q. I'm going to hand you what's been</p> <p>7 previously marked as Roxane Exhibit 41, and this</p> <p>8 is a document entitled Medicare Professional</p> <p>9 Reimbursement, Best Procedure -- Drug Pricing</p> <p>10 Procedure.</p> <p>11 Do you recognize this document as well?</p> <p>12 A. Yes.</p> <p>13 Q. And are these different formats for</p> <p>14 basically the same kind of document? I recognize</p> <p>15 they have different content in them. But I'm</p> <p>16 just trying to understand this idea of a drug</p> <p>17 pricing procedure. Is that a general type -- a</p> <p>18 type of document that you're familiar with?</p> <p>19 A. This -- I'm not sure about the first</p> <p>20 one that you gave me.</p> <p>21 Q. Meaning Roxane 100? Okay.</p> <p>22 A. Yes.</p>
<p style="text-align: right;">35</p> <p>1 classifying drugs as generics or brands</p> <p>2 differently as long as they came out on the same</p> <p>3 fee payment schedule?</p> <p>4 A. I never considered the generic and the</p> <p>5 brands. I thought we all were using the same</p> <p>6 instructions, looking that -- all the same, so I</p> <p>7 would not have even questioned it. If the fees</p> <p>8 came out the same, I wouldn't have gone any</p> <p>9 further.</p> <p>10 Q. Now, when you say the same</p> <p>11 instructions, what are you specifically referring</p> <p>12 to?</p> <p>13 A. The transmittals that I said earlier</p> <p>14 from CMS.</p> <p>15 Q. Now, are you familiar with -- with</p> <p>16 what has been referred to as Medicare</p> <p>17 Professional Drug Pricing Procedure, documents</p> <p>18 that have that title? Is that something you're</p> <p>19 familiar with?</p> <p>20 A. No.</p> <p>21 Q. I'm going to hand you what has been</p> <p>22 marked as -- previously marked as Roxane Exhibit</p>	<p style="text-align: right;">37</p> <p>1 Q. All right.</p> <p>2 A. Roxane 41 was when the DMERCs were</p> <p>3 trying to work together to establish that all of</p> <p>4 them had the same procedures, so there was input</p> <p>5 from all of the different DMERCs of how the</p> <p>6 pricing was done.</p> <p>7 Q. And this was a document, then, that</p> <p>8 all four DMERCs in some fashion would review and</p> <p>9 -- and provide input to?</p> <p>10 A. Yes, they worked on it together.</p> <p>11 Q. And is it a document that was revised</p> <p>12 and evolved over time?</p> <p>13 A. I believe that the information from</p> <p>14 this actually went into the Internet only</p> <p>15 manuals, Publication 100-04, Chapter 17, which is</p> <p>16 where our instructions are for drug pricing.</p> <p>17 Q. Can you repeat that publication number</p> <p>18 again?</p> <p>19 A. Publication 100-04, which is the</p> <p>20 Medicare claims processing manual.</p> <p>21 Q. And when you say Internet only</p> <p>22 manuals, what do you mean by that?</p>

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<p style="text-align: right;">38</p> <p>1 A. CMS guidance to the Medicare carriers 2 manuals went from a Medicare carriers manual, 3 which was a paper hard copy, to Internet only 4 manuals that are on the CMS website. 5 Q. Do you know when that transition to 6 the website occurred? 7 A. I do not. 8 Q. What would be your best estimate? 9 MR. FAUCI: Object to the form. 10 THE WITNESS: I would say between 2000 11 and 2002, but I'm -- that is just a guess. 12 BY MR. GORTNER: 13 Q. And would these manuals have been 14 available to the public, what I mean by that is 15 available to people that weren't Medicare carrier 16 personnel? 17 A. I believe that they're on the CMS 18 website, which is public, but I can't confirm 19 that anyone can look at them. 20 Q. What was the process by which these 21 drug pricing procedure documents would be 22 integrated into the -- the Medicare carriers</p>	<p style="text-align: right;">40</p> <p>1 MR. FAUCI: Object to the form. 2 THE WITNESS: I believe that the actual 3 document that you have here is what the DMERCs 4 sent as what they were doing. I don't think 5 these were the actual instructions, so we would 6 have actually followed the instructions that came 7 out based on this. 8 BY MR. GORTNER: 9 Q. And by the instructions, you're 10 referring to the Medicare carriers manual? 11 A. The carriers manual, the IOM. 12 Q. Let me stop you there. Just explain 13 what that acronym is. 14 A. Internet only manual. 15 Q. Okay. Anything else? 16 A. The CMS transmittals. 17 Q. Well, take a look at Roxane 100 real 18 quick, if you would. And on the first page, you 19 can see that it is exerting a section of the code 20 of federal regulations that establishes the 21 payment for Part B drugs. Do you see that in 22 italics?</p>
<p style="text-align: right;">39</p> <p>1 manual? How would that happen, if you know? 2 A. I do not. We provided the information 3 to CMS. 4 Q. And in terms of getting feedback from 5 the different DMERCs, do you recall whether there 6 were meetings or conference calls or some other 7 procedure by which comments or ideas could be 8 exchanged on this drug pricing procedure? 9 A. I believe it was e-mail and possibly 10 conference calls. 11 Q. What's your understanding of the -- of 12 the purpose of a drug pricing procedure document? 13 A. To try to get all four DMERCs using 14 the same process. 15 Q. Is it fair to say that, then, the 16 procedures in the drug pricing procedure document 17 were intended to be followed by all four DMERCs? 18 A. Yes. 19 Q. So these drug pricing procedure 20 documents outlined a process by which all four 21 DMERCs should have been pricing their drugs and 22 classifying their drugs, right?</p>	<p style="text-align: right;">41</p> <p>1 A. I do. 2 Q. And you can see that in the last 3 sentence of that excerpt from the code of federal 4 regulations it describes the payment for multiple 5 source drugs, which is basically that the average 6 wholesale price is defined as the lesser of the 7 median average price for all sources of generics; 8 or if the brand AWP is lower, that sets the 9 payment basis, right? 10 A. Yes. 11 Q. In a nutshell, what this -- what this 12 regulation is telling the DMERCs is that you pay 13 for generic drugs under Part B on either the 14 median of the generic AWP or the brand AWP if 15 that's lower; is that an accurate statement of 16 your understanding of the regulation? 17 A. You -- you set the fee -- or pay for 18 the -- the fee. I don't think it just says 19 generics. It would be any drugs that fall under 20 that code is going to be based on the lesser of 21 the median of the generics or the lowest brand. 22 Q. And then the -- the next section under</p>

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<p style="text-align: right;">42</p> <p>1 Scope, it says, "This procedure outlines the</p> <p>2 criteria used to calculate the quarterly</p> <p>3 reimbursement updates for Part A, Part B, DMERC,</p> <p>4 and SAD or SADMERC drugs." Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Now, could this document be an excerpt</p> <p>7 from -- from a manual, a carriers manual? Does it</p> <p>8 look like it's in that format?</p> <p>9 A. It does not look like it's in that</p> <p>10 format.</p> <p>11 Q. And you can see a little bit further</p> <p>12 down on that -- on that first page, there's a</p> <p>13 reference to a form number or a document number,</p> <p>14 and you see that it mentions a Transmittal AB</p> <p>15 9963. Do you see that?</p> <p>16 A. I do.</p> <p>17 Q. And that was some 1999 transmittal</p> <p>18 from HCFA; is that right?</p> <p>19 A. I would assume so.</p> <p>20 Q. Now, on the next page, which is Bates</p> <p>21 labeled AWP 034-0463, there's a heading at the</p> <p>22 top that says, "Step 2, identify drug sources."</p>	<p style="text-align: right;">44</p> <p>1 you would set the fee payment based on whichever</p> <p>2 one was lower?</p> <p>3 A. Based on -- with others</p> <p>4 considerations.</p> <p>5 Q. What does that mean?</p> <p>6 A. There is a piece missing here about</p> <p>7 the reduction. Once you determine the AWP, then</p> <p>8 you -- what you're going to use is the AWP,</p> <p>9 whether it's the median of the generics of the</p> <p>10 lowest brand, then during part of that time, it</p> <p>11 would get a 95 percent.</p> <p>12 Q. That's right. It paid 95 percent, not</p> <p>13 100 percent AWP in this time frame?</p> <p>14 A. Yes.</p> <p>15 Q. Now, the next bullet point down, which</p> <p>16 carries over to the next page, it states, "To</p> <p>17 determine if a drug is a generic or brand, look</p> <p>18 at the boldface uppercase name of the drug. If</p> <p>19 there's another name for the drug immediately</p> <p>20 below it in lower case letters (the generic</p> <p>21 name), the entries following are generally</p> <p>22 brands. If there is no lower case drug name</p>
<p style="text-align: right;">43</p> <p>1 And if you go to the second from the bottom</p> <p>2 bullet point on that same page, there's a</p> <p>3 paragraph that begins with, "If no generic forms</p> <p>4 of the drug exist, use all brands that exist for</p> <p>5 a specified dosage." Do you see that sentence?</p> <p>6 A. Yes.</p> <p>7 Q. And then the last sentence of that</p> <p>8 paragraph says, "During 1998, if a brand name</p> <p>9 source was lower than the median of generics, the</p> <p>10 lower brands were included in the median AWP</p> <p>11 calculation." Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And that was a different methodology</p> <p>14 for that one year; is that correct?</p> <p>15 A. That is correct.</p> <p>16 Q. And then in 1999, it became, pay at</p> <p>17 the lower of the median of the generic AWP's or</p> <p>18 the brand AWP if it's lower?</p> <p>19 A. That is correct.</p> <p>20 Q. And that's how you set payment rates</p> <p>21 up to 2004 at Cigna, that you would compare the</p> <p>22 median of the generic AWP's and the brand AWP, and</p>	<p style="text-align: right;">45</p> <p>1 immediately below the boldface uppercase name,</p> <p>2 the boldface uppercase name is the generic name,</p> <p>3 and all entries below are generics."</p> <p>4 Let me stop you there. You're familiar</p> <p>5 during your work with Cigna with that methodology</p> <p>6 of determining generics versus brands?</p> <p>7 A. Yes.</p> <p>8 Q. And you had seen that before in other</p> <p>9 drug pricing procedure guides as well?</p> <p>10 A. I don't think we actually had a guide,</p> <p>11 but, yes, I was trained on --</p> <p>12 Q. You were -- you were trained on this</p> <p>13 -- on this methodology?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And this was a methodology that</p> <p>16 was in place at least as of 1999, right?</p> <p>17 A. It was in 1999. I think that this is</p> <p>18 based on hard copy Red Book.</p> <p>19 Q. That's my next question is, is can you</p> <p>20 explain to me how this criteria -- criteria was</p> <p>21 implemented at Cigna?</p> <p>22 A. I don't have a Red -- on the --</p>

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<p style="text-align: right;">46</p> <p>1 Q. Would it help you if you had a Red</p> <p>2 Book?</p> <p>3 A. Please.</p> <p>4 Q. Why don't -- why don't we get it?</p> <p>5 MR. GORTNER: Why don't we take a quick</p> <p>6 break. We've gone about an hour. Let's take a</p> <p>7 quick break. And then we can kind of walk</p> <p>8 through a hard copy Red Book in reference to that</p> <p>9 criteria. Okay?</p> <p>10 THE WITNESS: Okay.</p> <p>11 THE VIDEOGRAPHER: Going off the</p> <p>12 record, time is 9:54.</p> <p>13 (Brief recess observed.)</p> <p>14 THE VIDEOGRAPHER: Back on the record,</p> <p>15 time is 10:01.</p> <p>16 (Marked Exhibit Roxane 261.)</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. Ms. Helton, I've handed you what we've</p> <p>19 marked as Roxane Exhibit 261. This is an excerpt</p> <p>20 from the 2001 annual Red Book, the printed</p> <p>21 version, and I wanted to draw your attention to</p> <p>22 what's Page 368 in the upper left-hand corner of</p>	<p style="text-align: right;">48</p> <p>1 entire entry is in bold and capitals, correct?</p> <p>2 A. Correct.</p> <p>3 Q. And then underneath it, it has an</p> <p>4 entry in lowercase for the generic chemical name</p> <p>5 ipratropium bromide, right?</p> <p>6 A. Yes.</p> <p>7 Q. And is it fair to say that if you were</p> <p>8 looking at this document and applying the</p> <p>9 criteria that we just discussed on the drug</p> <p>10 pricing procedure document, that would meet the</p> <p>11 criteria for a brand drug because it has a</p> <p>12 heading all in capital bold up top with the</p> <p>13 generic name in lowercase underneath it?</p> <p>14 A. Yes, it has a -- the bold cap is a</p> <p>15 different name, and then the generic name is in</p> <p>16 lowercase. So the cap is different from the</p> <p>17 generic, so, yes, it is a brand name.</p> <p>18 Q. And that's the way that you would</p> <p>19 apply that criteria at Cigna if you were looking</p> <p>20 at a printed Red Book; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. And looking over similar to the -- to</p>
<p style="text-align: right;">47</p> <p>1 this document. And if you look on the left-hand</p> <p>2 column about halfway down, there is an entry for</p> <p>3 ipratropium bromide. Do you see that in bold?</p> <p>4 A. Yes.</p> <p>5 Q. And it continues listing a variety of</p> <p>6 ipratropium bromides from different manufacturers</p> <p>7 on that left-hand column and over it about</p> <p>8 halfway on the middle column of Page 368. Do you</p> <p>9 see that?</p> <p>10 A. Yes.</p> <p>11 Q. And now I wanted to discuss this --</p> <p>12 this criteria for classifying generics versus</p> <p>13 brand drugs that we just looked at in the drug</p> <p>14 pricing procedure document. Okay? And let me</p> <p>15 know if I'm understanding how that criteria</p> <p>16 worked.</p> <p>17 But in essence, if you look at the</p> <p>18 entry for Ipratropium Bromide Hydrous, which is</p> <p>19 in the middle of that second column, do you see</p> <p>20 that?</p> <p>21 A. Yes.</p> <p>22 Q. And what you see there is that that</p>	<p style="text-align: right;">49</p> <p>1 the next page, in the thirdhand column over on</p> <p>2 the -- on the page marked 362, there's an entry</p> <p>3 there for Inderal, can you see that? And</p> <p>4 underneath it, it has an entry in lowercase for</p> <p>5 propranolol hydrochloride. That would also be</p> <p>6 considered a brand under this criteria?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Now, I wanted you to go back to</p> <p>9 Page 368 and look at the entry for the Roxane</p> <p>10 ipratropium bromides above. If you look right</p> <p>11 above the -- the entry for Zenith Goldline, you</p> <p>12 can see that Roxane is in parens in that middle</p> <p>13 column on Page 368?</p> <p>14 A. Yes.</p> <p>15 Q. And you see that there's six NDCs that</p> <p>16 are listed there. Three of them up top have the</p> <p>17 middle designation of 8402, and then three at the</p> <p>18 bottom have the middle designation of NDC 8404.</p> <p>19 Do you see those?</p> <p>20 A. Yes.</p> <p>21 Q. And using the criteria that we just</p> <p>22 talked about in that drug pricing procedure,</p>

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14 (Pages 50 to 53)

<p style="text-align: right;">50</p> <p>1 Cigna would classify all six of these NDCs as 2 generics, wouldn't it? 3 A. Using the hard copy, yes. 4 Q. Okay. And that criteria would be in 5 effect all the way up to 2004 when the Medicare 6 policy changed, or would it continue up until 7 today? 8 MR. FAUCI: Object to the form. 9 THE WITNESS: If we were using the hard 10 copy, yes. But we switched to the CD, so the CD 11 is different format. 12 BY MR. GORTNER: 13 Q. Okay. And we'll talk about the CDs in 14 just a moment. But just so I understand how it 15 worked at Cigna, it -- you would apply the rule 16 regarding capitalization of the product to 17 determine whether it was a generic or brand when 18 you were relying on the hard copy Red Book; is 19 that correct? 20 MR. FAUCI: Objection to the form. 21 THE WITNESS: The capitalization of the 22 product helps you determine. You would apply the</p>	<p style="text-align: right;">52</p> <p>1 ipratropium bromide. 2 Q. Right. 3 A. Okay. I have to consider that the 4 Ipratropium Bromide Hydrous, based on statutes, 5 is different than the generic name. So if it's 6 different than the generic name, it's a brand. 7 Q. Let me stop you there. Were there any 8 exceptions to that rule that Cigna applied? 9 A. I can't think of any for -- for DME. 10 Q. We deposed Ms. Stone from the Palmetto 11 DMERC a couple days ago, and she mentioned that 12 there may be situations where the name of the 13 drug has something more than just the generic 14 name in it. In other words, it might be a drug 15 that has ipratropium bromide hydrochloride, for 16 instance. 17 And there would be instances where the 18 additional term that was in the name of the drug 19 was related to being a dilutant, for instance. 20 They might classify that drug as a -- as a 21 generic or at least have a discussion about 22 whether it should be a generic or a brand.</p>
<p style="text-align: right;">51</p> <p>1 rules that are in the CMS guidelines. 2 BY MR. GORTNER: 3 Q. Well, how would those two work 4 together? I'm trying to understand. You have a 5 -- the drug pricing procedure rule there 6 regarding limited capitalization and whether it 7 had a lowercase generic name underneath it, 8 correct? How would that rule work in conjunction 9 with the CMS rule? 10 A. You have to compare the two and see. I 11 don't see any conflict with it here, but I would 12 have to evaluate each one individually and see if 13 there was. 14 Q. Okay. And how would you do that? Can 15 you explain that? 16 A. I'm looking at what I see here, and I 17 don't see anything here that would tell me that 18 it's different, so -- based on this, I don't see 19 any different names added to, so I would say it's 20 the same. 21 Like the Ipratropium Bromide Hydrous 22 and then the generic name underneath it is</p>	<p style="text-align: right;">53</p> <p>1 Was there anything akin to that at 2 Cigna? 3 A. I don't think that that was considered 4 brand -- a brand conversation. I'm thinking that 5 those are still considered generics. But 6 sometimes when you're doing arrays for drugs, the 7 medical directors would make determinations as 8 to, if you don't have a drug that meets the 9 code's description specifically, that you may 10 have to -- there's -- like a chloride may have to 11 be used for that drug. 12 Q. I'm not sure I understand that 13 exactly. Can you -- 14 A. I don't have any codes here to 15 explain. Some of the drugs, especially for the 16 inhalation drugs, didn't have inhalation formats 17 that were -- the name of the drug was just 18 strictly the generic as in the HCPCS description. 19 You could not find any products that met that 20 description. 21 So the medical directors would say that 22 a different type of drug, like a hydrochloride,</p>

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15 (Pages 54 to 57)

<p style="text-align: right;">54</p> <p>1 was actually what was being used for that</p> <p>2 inhalation.</p> <p>3 And so we would pull in the products</p> <p>4 for that -- that drug into the array because we</p> <p>5 couldn't find the other.</p> <p>6 Q. Well, can you give me an example of a</p> <p>7 drug that would have -- because I'm just trying</p> <p>8 to understand, are you referring to the fact that</p> <p>9 you would add a term to the drug name so that it</p> <p>10 would match the -- the HCFA description or</p> <p>11 whether you would give it an entirely different</p> <p>12 name? I'm just trying to understand what you're</p> <p>13 referring to.</p> <p>14 A. I don't actually have any description</p> <p>15 -- anything with me here to give you examples of</p> <p>16 it. The -- when you're talking about like sulfide</p> <p>17 and hydrochloride and things like that that are</p> <p>18 added but they -- they're part -- they're a</p> <p>19 generic name, but they're a little bit different</p> <p>20 than the generic name of the drug, if you don't</p> <p>21 have any products that fall under that generic</p> <p>22 name, then we would have to ask for assistance</p>	<p style="text-align: right;">56</p> <p>1 brand?</p> <p>2 A. I do not.</p> <p>3 Q. Now, with respect to the -- the HCFA</p> <p>4 transmittal that you're referring to in</p> <p>5 classifying a generic or a brand, what was your</p> <p>6 understanding of what that criteria was for</p> <p>7 determining --</p> <p>8 A. If --</p> <p>9 Q. -- let me finish the question --</p> <p>10 determining whether a drug was a generic or a</p> <p>11 brand?</p> <p>12 A. When you're looking at the description</p> <p>13 of the drug, if the drug is other than -- or the</p> <p>14 name is other than the generic name of the drug,</p> <p>15 if it has something added to it, then it would be</p> <p>16 considered a brand.</p> <p>17 Q. Okay. So let's take the simplest</p> <p>18 example. If a drug is called Atrovent and the</p> <p>19 generic chemical name is ipratropium bromide,</p> <p>20 Atrovent is clearly a name other than the generic</p> <p>21 chemical name, and you would classify that as a</p> <p>22 brand?</p>
<p style="text-align: right;">55</p> <p>1 from the medical directors, and they would</p> <p>2 determine which products actually were being used</p> <p>3 under those codes.</p> <p>4 Q. Okay. I think I understand what</p> <p>5 you're saying now.</p> <p>6 Would the medical directors ever be</p> <p>7 involved in the process of helping you determine</p> <p>8 whether a drug was a generic or a brand drug?</p> <p>9 A. No.</p> <p>10 Q. Would anyone other than, in this</p> <p>11 instance, you who was involved with grading the</p> <p>12 arrays, be involved in the process of determining</p> <p>13 whether a drug was a generic or a brand?</p> <p>14 A. For Cigna? No. We -- I mean, we</p> <p>15 might have discussed some on the conference</p> <p>16 calls.</p> <p>17 Q. Do you have any recollection of that?</p> <p>18 A. No.</p> <p>19 Q. Do you know whether any of the other</p> <p>20 DMERCs had a process by which a medical director</p> <p>21 or some other staff would be consulted with to</p> <p>22 determine whether a drug was a generic or a</p>	<p style="text-align: right;">57</p> <p>1 A. Yes.</p> <p>2 Q. And you're familiar with that drug,</p> <p>3 aren't you?</p> <p>4 A. Yes.</p> <p>5 Q. And you routinely classify Atrovent as</p> <p>6 a brand at all pertinent times in the Cigna</p> <p>7 arrays?</p> <p>8 A. Yes.</p> <p>9 Q. Now, in situations where you have the</p> <p>10 generic chemical name, like ipratropium bromide,</p> <p>11 in the drug title and something additional, is it</p> <p>12 your testimony that you considered that to be</p> <p>13 other than the generic chemical name?</p> <p>14 A. Yes.</p> <p>15 Q. And that was the criteria you were</p> <p>16 looking at. If it was different in any way from</p> <p>17 simply the words ipratropium bromide, you</p> <p>18 categorized it as a brand in your arrays?</p> <p>19 A. Yes.</p> <p>20 Q. Now, looking at this 2001 annual Red</p> <p>21 Book printout for the Roxane NDCs, I'll represent</p> <p>22 to you that the NDCs that have the 8404 in the</p>

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16 (Pages 58 to 61)

<p style="text-align: right;">58</p> <p>1 middle, the three lower NDCs on that Page 368 of</p> <p>2 the Red Book, those represent the NDCs with the</p> <p>3 Novaplus label ipratropium bromide. Okay?</p> <p>4 A. Okay.</p> <p>5 Q. And you'd agree with me that using the</p> <p>6 HCFA criteria that you're referring to, which is</p> <p>7 if the product name is something other than the</p> <p>8 generic chemical name, you would classify those</p> <p>9 three Novaplus NDCs as a generic, wouldn't you?</p> <p>10 MR. FAUCI: Object to the form.</p> <p>11 THE WITNESS: Based on using this</p> <p>12 information in Red Book, it is listed as</p> <p>13 ipratropium bromide with just the manufacturer.</p> <p>14 So based on this, it only is ipratropium bromide.</p> <p>15 So I would -- based on just that it is the</p> <p>16 generic name, I would have classified these as a</p> <p>17 generic.</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. To be clear, you would have classified</p> <p>20 the Novaplus label ipratropium bromide NDCs as a</p> <p>21 generic under either one of the two criteria</p> <p>22 we're talking about. Either based upon the</p>	<p style="text-align: right;">60</p> <p>1 CDs.</p> <p>2 Q. Can you explain for me the reasons why</p> <p>3 you switched to the quarterly CDs from the</p> <p>4 printed versions?</p> <p>5 A. It was determined by the four DMERCs</p> <p>6 together that the quarterly CDs were easier and</p> <p>7 faster than the hard copies, so all four agreed</p> <p>8 to go with the quarterly CDs.</p> <p>9 Q. That's because on a quarterly CD you</p> <p>10 can do searches and get right to the product and</p> <p>11 don't have to be flipping through a book?</p> <p>12 A. That is correct.</p> <p>13 Q. There's a real convenience factor to</p> <p>14 those CDs versus the annual hard copies, right?</p> <p>15 A. The CDs also had the ability to search</p> <p>16 by NDC number.</p> <p>17 Q. Do you recall at what point in 2000</p> <p>18 the switch was made? Was it later 2000? Mid?</p> <p>19 A. I actually think -- I think it was the</p> <p>20 first or second quarter of 2000. I think the</p> <p>21 first CD we had was October in '99, which would</p> <p>22 have come into play with the January 2000.</p>
<p style="text-align: right;">59</p> <p>1 capitalization format in the Red Book or on the</p> <p>2 HCFA criteria with regard to the generic name,</p> <p>3 they would be classified as generics based upon</p> <p>4 this 2001 annual Red Book printout?</p> <p>5 MR. FAUCI: Object to the form.</p> <p>6 THE WITNESS: Based on this where it's</p> <p>7 strictly listed as ipratropium bromide only, yes,</p> <p>8 I would have classified it as a generic.</p> <p>9 BY MR. GORTNER:</p> <p>10 Q. You spoke a moment ago that -- that</p> <p>11 Cigna transitioned to different formats of the</p> <p>12 Red Book over time; is that right?</p> <p>13 A. Yes.</p> <p>14 Q. Can you explain for me generally what</p> <p>15 materials Red -- of Red Book Cigna was using over</p> <p>16 time where we can, you know, begin with the late</p> <p>17 1990s up to 2004 if it's easier for you to</p> <p>18 recollect that.</p> <p>19 A. The late 1990s we were using the</p> <p>20 annual and the monthly hard copies.</p> <p>21 Q. Okay.</p> <p>22 A. 2000 we started using the quarterly</p>	<p style="text-align: right;">61</p> <p>1 Q. You're not sure one way or the other?</p> <p>2 A. I'm not really sure.</p> <p>3 Q. So up until some point in 2000, you</p> <p>4 were using the annual Red Book like the excerpt</p> <p>5 that we have right here marked as Roxane Exhibit</p> <p>6 261, right?</p> <p>7 A. Yes.</p> <p>8 Q. So you're familiar with this entry for</p> <p>9 ipratropium bromide, right?</p> <p>10 A. Yes.</p> <p>11 Q. And the decision to change to</p> <p>12 different Red Book formats was a decision the</p> <p>13 four DMERCs collectively made?</p> <p>14 A. Yes.</p> <p>15 Q. The Red Book CDs required a</p> <p>16 subscription, didn't they?</p> <p>17 A. Yes.</p> <p>18 Q. You'd have to pay, what, a quarterly</p> <p>19 or an annual fee?</p> <p>20 A. I think it was annual.</p> <p>21 Q. So the Red Book CDs weren't something</p> <p>22 that -- that the general public would just have</p>

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<p style="text-align: right;">62</p> <p>1 access to? You would have to actually sign up</p> <p>2 and pay Red Book to be able to look at these CDs;</p> <p>3 is that correct?</p> <p>4 MR. FAUCI: Object to the form.</p> <p>5 THE WITNESS: From my standpoint, yes,</p> <p>6 but I didn't look anywhere else, so I don't know.</p> <p>7 BY MR. GORTNER:</p> <p>8 Q. Now, during your time constructing the</p> <p>9 DMERC pricing arrays for Cigna, did Cigna always</p> <p>10 look to the Red Book publishing compendium?</p> <p>11 A. Yes.</p> <p>12 Q. Do you have any understanding as to</p> <p>13 why Cigna relied exclusively on the Red Book</p> <p>14 compendium?</p> <p>15 A. I do not know initially why Cigna. It</p> <p>16 was selected prior to my coming in. Going</p> <p>17 forward when the DMERCs started working together,</p> <p>18 that was the source that all four DMERCs selected</p> <p>19 as the one that they all four had, so it was</p> <p>20 determined that that was the one we would use.</p> <p>21 Q. Do you think it was based on -- on the</p> <p>22 historical use of the Red Book? Is that the</p>	<p style="text-align: right;">64</p> <p>1 and Blue Book were some -- a couple of them, but</p> <p>2 I don't remember all of them.</p> <p>3 Q. Now, you're familiar with</p> <p>4 FirstDataBank Blue Book?</p> <p>5 A. I have not actually ever worked with</p> <p>6 it.</p> <p>7 Q. You know it's out there, though,</p> <p>8 right?</p> <p>9 A. Yes.</p> <p>10 Q. Do you know if Medicaid programs use</p> <p>11 it?</p> <p>12 A. I do not know.</p> <p>13 Q. And how about the -- the Medispan</p> <p>14 publishing compendia?</p> <p>15 A. I have never used it.</p> <p>16 Q. But you're aware that there are these</p> <p>17 other compendia that are out there, right?</p> <p>18 A. Yes.</p> <p>19 Q. And you're aware during your time</p> <p>20 constructing the arrays for Cigna that you were</p> <p>21 authorized to look at other compendia should you</p> <p>22 choose to, right?</p>
<p style="text-align: right;">63</p> <p>1 reason you think?</p> <p>2 A. I would think that. Like I said, I</p> <p>3 don't know exactly why we started with the Red</p> <p>4 Book. It was one of the compendia in the CMS</p> <p>5 regulations that we could use. I don't know</p> <p>6 specifically why that one was chosen.</p> <p>7 For the DMERCs going forward where we</p> <p>8 wanted to all be on the same page, the same</p> <p>9 coordination, we all agreed to use Red Book. It</p> <p>10 was the -- the one that all four DMERCs already</p> <p>11 had.</p> <p>12 Q. So as far -- as far as you knew, there</p> <p>13 wasn't anything special about Red Book in the</p> <p>14 sense that it had more accurate pricing or better</p> <p>15 pricing than other compendia as far as you knew?</p> <p>16 A. I don't know.</p> <p>17 Q. Now, you -- you said a moment ago that</p> <p>18 Red Book was one of the sources that HCFA allowed</p> <p>19 DMERCs to look to for -- for drug pricing. What</p> <p>20 were the other sources?</p> <p>21 A. I believe that it changed through the</p> <p>22 years, so I can't say for sure. I think Medispan</p>	<p style="text-align: right;">65</p> <p>1 A. Yes.</p> <p>2 Q. And did the internal DMERC decision to</p> <p>3 rely on Red Book require you to only look at Red</p> <p>4 Book, or was that simply an agreement that was</p> <p>5 adhered to but that you still had discretion to</p> <p>6 look at other things?</p> <p>7 A. I don't really know. At the time,</p> <p>8 Barbara Douglas was the one who worked out, so --</p> <p>9 for Cigna, we only looked at Red Book. I can't</p> <p>10 say whether the other ones looked at other</p> <p>11 things.</p> <p>12 Q. Okay. But from what you just told me</p> <p>13 a moment ago, it sounds like you -- you never</p> <p>14 looked to the FirstDataBank Blue Book or Medispan</p> <p>15 book to help determine whether drugs were generic</p> <p>16 or brands, for instance?</p> <p>17 A. I did not.</p> <p>18 MR. GORTNER: Let's take a quick break</p> <p>19 to change tapes. Okay?</p> <p>20 THE WITNESS: Okay.</p> <p>21 THE VIDEOGRAPHER: Here marks the end</p> <p>22 of Tape No. 1. Going off the record, time is</p>

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<p style="text-align: right;">66</p> <p>1 10:24. 2 (Brief recess observed.) 3 THE VIDEOGRAPHER: Back on the record. 4 Here marks the beginning of Tape No. 2. Time is 5 10:29. 6 BY MR. GORTNER: 7 Q. Ms. Helton, going back to the Medicare 8 drug pricing procedure document, which is Roxane 9 100 that we looked at a moment ago, if you could 10 turn to Page 3 of that document, just following 11 up on the -- the criteria for distinguishing 12 between brand and generics, if you look at the 13 last sentence of that paragraph on the top of 14 Page 3, it reads, "If there is a question as to 15 whether a drug is brand or generic, consult the 16 PDR," which I think means Physicians' Desk 17 Reference, "generics book, telephone the drug 18 company, or Red Book," and it gives an 800 number 19 for Red Book. 20 At any point during your classification 21 of drugs as brand or generics, did you, in fact, 22 consult the PDR generics?</p>	<p style="text-align: right;">68</p> <p>1 the document. I don't know who created the 2 document. I can't say that this is the document 3 that is in Cigna's book of what instructions we 4 have. 5 Q. But does this -- does this description 6 of -- of the criteria of a generic and brand and 7 that option to contact Red Book or the drug 8 company, are those terms generally familiar to 9 you within Cigna's manual even if the precise 10 words might be different? 11 MR. FAUCI: Object to the form. 12 THE WITNESS: I would think that -- I 13 don't have a precise manual, so if I had a 14 question between generic and brand, I am aware 15 that there are options to try to find out. 16 BY MR. GORTNER: 17 Q. Okay. So let's set aside the 18 specifics of the document. 19 In terms of your procedure when you 20 were constructing the Cigna arrays, during that 21 time period of constructing the arrays, you were 22 aware that you had options to contact Red Book or</p>
<p style="text-align: right;">67</p> <p>1 A. I did not. 2 Q. Did anyone on your staff do so, as far 3 as you know? 4 A. Not that I'm aware of. 5 Q. How about ever telephone a drug 6 company to understand whether a drug was a 7 generic or a brand? 8 A. No. 9 Q. Or call Red Book itself? 10 A. No. 11 Q. But -- but during the time you were 12 creating these arrays, you knew that this option 13 was available to you, that you could consult a 14 PDR generics or call a drug company or the Red 15 Book? 16 A. I knew that there were options if we 17 needed help. I would not say that this procedure 18 is mine, so -- but, yes, I am aware of different 19 options. 20 Q. When you say I'm not -- this procedure 21 is not mine, what do you mean by that? 22 A. As before, the Roxane 100, I've seen</p>	<p style="text-align: right;">69</p> <p>1 the drug company if you -- if you so chose, 2 right? 3 A. Yes. 4 Q. And you could call them up to clarify 5 if -- if any of their drugs was a generic or a 6 brand, right? 7 A. Yes. 8 Q. Now, at some point in 2000, you 9 transitioned to using the Red Book CD-ROMs for 10 helping you determine the prices for drugs; is 11 that right? 12 A. That's right. 13 Q. Did you use any other Red Book in 14 addition to the CD-ROMs? For instance, did you 15 rely -- still rely on the monthly updates? 16 A. We did still use the monthly updates. 17 Q. So you did still have hard copies that 18 you used in addition to the CD-ROMs; is that 19 right? 20 A. That is correct. 21 Q. And with respect to the hard copies, 22 this criteria we're talking about in the drug</p>

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<p style="text-align: right;">70</p> <p>1 pricing procedure of the capitalization</p> <p>2 conventions of Red Book would still be one of the</p> <p>3 criteria you would look to to classify drugs as</p> <p>4 generic or brands?</p> <p>5 MR. FAUCI: Object to the form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. GORTNER:</p> <p>8 Q. Let's take a look at the -- the Red</p> <p>9 Book CD-ROMs. I'm going to hand you what we will</p> <p>10 mark as Roxane Exhibit 262.</p> <p>11 (Marked Exhibit Roxane 262.)</p> <p>12 MR. GORTNER: For the record, we've</p> <p>13 previously also marked this as Roxane Exhibit</p> <p>14 255.</p> <p>15 BY MR. GORTNER:</p> <p>16 Q. This, I'll represent to you, are a</p> <p>17 series of documents that we received from you or</p> <p>18 from DOJ counsel just last week. I'll ask you</p> <p>19 just to quickly flip through and see if you</p> <p>20 recognize these documents.</p> <p>21 I'll point you to a specific page, and</p> <p>22 I'll represent that those are a complete version</p>	<p style="text-align: right;">72</p> <p>1 the old DMERC, we still had the hold order for</p> <p>2 documentation for drug pricing, and we pulled</p> <p>3 boxes back from the warehouse that we thought</p> <p>4 would be pertinent to that hold document.</p> <p>5 Q. This was in 2006?</p> <p>6 A. Yes.</p> <p>7 Q. And this is one of the boxes that had</p> <p>8 been pulled in 2006?</p> <p>9 A. Yes.</p> <p>10 Q. And it had been pulled to where?</p> <p>11 A. To that cabinet in front of my desk.</p> <p>12 Q. Okay. So from -- since 2006, it was</p> <p>13 in that cabinet in front of your desk?</p> <p>14 A. Yes.</p> <p>15 Q. Now, you may recall that we spoke</p> <p>16 earlier today about the initial series of</p> <p>17 documents that Cigna had produced in this</p> <p>18 litigation, which included that HCFA transmittal</p> <p>19 you referred to. Do you remember that?</p> <p>20 A. Yes.</p> <p>21 Q. Why was it that these documents</p> <p>22 weren't included in that production?</p>
<p style="text-align: right;">71</p> <p>1 of the documents that we received. But</p> <p>2 generally, do they appear to be the documents</p> <p>3 that you provided to counsel?</p> <p>4 A. Yes.</p> <p>5 Q. Can you explain for me how you located</p> <p>6 these documents?</p> <p>7 A. I have some boxes of drug pricing</p> <p>8 information, and I pulled this out of those</p> <p>9 boxes.</p> <p>10 Q. Where were those boxes located?</p> <p>11 A. They're currently located in my</p> <p>12 building in front of my desk. We had pulled them</p> <p>13 back from the warehouse.</p> <p>14 Q. Before -- before they were in your</p> <p>15 office, then, they had been in a warehouse where</p> <p>16 Cigna stores documents?</p> <p>17 A. Yes.</p> <p>18 Q. And where is that warehouse located?</p> <p>19 A. I don't know.</p> <p>20 Q. Now, how did -- how did you come about</p> <p>21 retrieving those documents from the warehouse?</p> <p>22 A. In 2006 when Cigna transitioned out of</p>	<p style="text-align: right;">73</p> <p>1 MR. FAUCI: Object to the form.</p> <p>2 THE WITNESS: The way that we</p> <p>3 interpreted the documentation was that you wanted</p> <p>4 the spreadsheets and how we used AWP.</p> <p>5 We provided the spreadsheets -- the</p> <p>6 spreadsheet itself was already provided</p> <p>7 electronically. We did not interpret that to</p> <p>8 mean that you wanted all of our resources, which</p> <p>9 are copyrighted, such as Red Book, so we did not</p> <p>10 provide.</p> <p>11 BY MR. GORTNER:</p> <p>12 Q. Now, how about the Red Book CDs? Those</p> <p>13 -- as you may recall, a subset of those was</p> <p>14 produced a little bit earlier this summer. Is it</p> <p>15 the same situation with Red Book CDs? Were they</p> <p>16 kept in a similar location?</p> <p>17 A. The CDs were not kept in a similar</p> <p>18 location. The CDs are loaded to our mainframes;</p> <p>19 therefore, they are maintained and secured by the</p> <p>20 people who maintain the mainframe. I don't know</p> <p>21 exactly what the designation is for that person.</p> <p>22 And when we first started Red Book,</p>

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20 (Pages 74 to 77)

<p style="text-align: right;">74</p> <p>1 they were diskettes loaded to an individual user 2 machine. Those were not maintained because as 3 each Red Book comes out, subsequent one, it -- 4 you get rid of the previous one.</p> <p>5 Q. Okay.</p> <p>6 A. You only maintain the current. So the 7 ones that we produced were the ones that were the 8 multiuser license that had been at one time 9 loaded to our mainframes while the subscriptions 10 were valid. They had been maintained in the 11 cabinet, but the subscriptions had expired, so we 12 cannot access them. They're no longer on our 13 system.</p> <p>14 Q. So there's some subset of CDs where 15 that -- that information is no longer retrievable 16 on your end; is that right?</p> <p>17 A. I would think that -- some of the CDs 18 it's no longer retrievable on our end, yes. And 19 then some of the earlier versions we don't have 20 at all.</p> <p>21 Q. Okay.</p> <p>22 A. They've already been destroyed.</p>	<p style="text-align: right;">76</p> <p>1 is that correct?</p> <p>2 A. Yes.</p> <p>3 Q. Then let's take a look at the page 4 that begins CIGNA-0109. It's the lower right 5 Bates label. That -- that page appears to be an 6 array for ipratropium bromide constructed by 7 Cigna, and it has a date on the lower right of 8 December 12, 2000. Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Then at the very bottom center, 11 there's a phrase that says, "Confidential, 12 unpublished property of Cigna. Do not duplicate 13 or distribute. Use and distribution limited 14 solely to authorized personnel, 2000, Cigna." 15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And I take it that then these arrays 18 were arrays that were kept internally at Cigna 19 only?</p> <p>20 A. Yes.</p> <p>21 Q. So you didn't publish these up on a 22 website or distribute them out to providers, for</p>
<p style="text-align: right;">75</p> <p>1 Q. So at some point during the summer, 2 you -- you contacted someone at your IT 3 department to try to locate off your server the 4 Red Book CD information that was still available?</p> <p>5 A. Not off the server because they're no 6 longer maintained there. Only the current 7 version is maintained. We had to contact someone 8 in the IT area to see if they had the older 9 versions anywhere in storage.</p> <p>10 Q. Okay. Are there other documents, 11 either electronic or hard copy, that -- that 12 relate to your pricing arrays that have not been 13 produced in this litigation?</p> <p>14 A. Other than the actual Red Book?</p> <p>15 Q. Right.</p> <p>16 A. No.</p> <p>17 Q. Now let's take a look at Roxane 18 Exhibit 262. This appears to be a printout of -- 19 of Cigna arrays from 1999 through 2004. And 20 behind each Cigna array, it appears that you have 21 printed out in -- and attached Red Book CD-ROM 22 information with respect to ipratropium bromide;</p>	<p style="text-align: right;">77</p> <p>1 instance?</p> <p>2 A. No.</p> <p>3 Q. Is it fair to say that the -- that the 4 only information that would be publicly available 5 from the Cigna arrays would be the actual fee 6 payment that you set for ipratropium bromide?</p> <p>7 A. Yes.</p> <p>8 MR. FAUCI: Object to the form.</p> <p>9 BY MR. GORTNER:</p> <p>10 Q. And individuals who were not part of 11 the -- the Cigna DMERC or individuals connected 12 with other DMERCs wouldn't know the specific 13 drugs that you placed in each particular portion 14 of the array; is that right?</p> <p>15 A. If I had a dispute with one of the 16 other -- or in the fee that I came up with with 17 one of the other DMERCs, if we had a discrepancy 18 then they could know how I put on those 19 conference calls.</p> <p>20 They also would have the information 21 that's in the lower -- with the KO and KPs, that 22 lower left-hand corner, all four DMERCs would</p>

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21 (Pages 78 to 81)

<p style="text-align: right;">78</p> <p>1 have had that calculation.</p> <p>2 Q. But how about anyone else outside of</p> <p>3 the DMERCs?</p> <p>4 A. No.</p> <p>5 Q. They wouldn't have access to that</p> <p>6 information of how you put a particular drug in a</p> <p>7 particular generic versus brand array, for</p> <p>8 instance?</p> <p>9 A. I would say on a routine basis, no. I</p> <p>10 don't know if someone like you subpoenaed the</p> <p>11 documents.</p> <p>12 Q. Okay. So through a formal subpoena,</p> <p>13 those documents might be produced?</p> <p>14 A. Yes.</p> <p>15 Q. I'm just trying to establish, in the</p> <p>16 normal course, a manufacturer like Roxane, for</p> <p>17 instance, as far as you know, wouldn't have a</p> <p>18 publicly available source to be able to look and</p> <p>19 see, Oh, you put our Roxane ipratropium bromide</p> <p>20 in the generic array of Cigna, and you put the</p> <p>21 Novaplus Ipratropium Bromide in the brand array?</p> <p>22 A. Correct.</p>	<p style="text-align: right;">80</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And then it looks like in the -- in</p> <p>4 the pages that follow it that begin with Bates</p> <p>5 label CIGNA 01111 through CIGNA 01119, those are</p> <p>6 printouts from the Red Book CD-ROM of what's</p> <p>7 called detailed product information for each one</p> <p>8 of those ipratropium bromide NDCs; is that right?</p> <p>9 A. Yes.</p> <p>10 Q. And that was just another -- a tab you</p> <p>11 could click on the Red Book CD, for instance?</p> <p>12 A. Yes.</p> <p>13 Q. And with respect to this information,</p> <p>14 the information that was on the product</p> <p>15 information list and all the detailed product</p> <p>16 information, that was all available to you as you</p> <p>17 were constructing the Cigna arrays from</p> <p>18 ipratropium bromide, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you're familiar with the</p> <p>21 information contained on -- on this Red Book</p> <p>22 CD-ROM as you've printed it out here, right?</p>
<p style="text-align: right;">79</p> <p>1 Q. They wouldn't know that, right?</p> <p>2 A. That is correct.</p> <p>3 Q. Correct?</p> <p>4 A. Correct, would not.</p> <p>5 Q. If you could look at the next page,</p> <p>6 which is Bates labeled 01110, and this appears to</p> <p>7 be a printout from the October 2000 Red Book for</p> <p>8 Windows CD that lists all the products associated</p> <p>9 with ipratropium bromide; is that right?</p> <p>10 A. Yes. The products that I selected.</p> <p>11 Q. Okay. In -- in this particular sheet</p> <p>12 that we're looking at, what would you have</p> <p>13 selected to get this particular printout from the</p> <p>14 Red Book CD?</p> <p>15 A. I would have selected solution .02</p> <p>16 percent.</p> <p>17 Q. That -- does that refer -- that refers</p> <p>18 to a specific J-code or HCPCS?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. So for that particular</p> <p>21 solution, this is -- these are all the -- the</p> <p>22 listings in the Red Books CD that you can see,</p>	<p style="text-align: right;">81</p> <p>1 A. Yes.</p> <p>2 Q. Okay. Now, taking a look at CIGNA</p> <p>3 01111, the detailed product information screens, I</p> <p>4 just want to talk to you a little bit about these</p> <p>5 screens. The first entry there has the product</p> <p>6 name for Atrovent, right?</p> <p>7 A. Yes.</p> <p>8 Q. And then underneath it, it has a</p> <p>9 generic name for ipratropium bromide, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And you knew, didn't you, that the</p> <p>12 generic name for these products was ipratropium</p> <p>13 bromide at all pertinent times?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And Atrovent obviously is a</p> <p>16 different kind of name than ipratropium bromide?</p> <p>17 A. Yes.</p> <p>18 Q. And that's why based upon the Red Book</p> <p>19 CD-ROM you would classify it as a brand, correct?</p> <p>20 A. Yes, based on this and CMS</p> <p>21 instructions.</p> <p>22 Q. Now, you see a -- that there's also a</p>

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22 (Pages 82 to 85)

<p style="text-align: right;">82</p> <p>1 field that Red Book provided to you throughout</p> <p>2 this time that is labeled Generic and has a Y/N.</p> <p>3 Did you understand that to be yes or no generic</p> <p>4 field?</p> <p>5 A. Yes.</p> <p>6 Q. And it tells you here that it -- that</p> <p>7 Red Book is classifying Atrovent as a brand drug,</p> <p>8 right, because it has an N or a no next to the</p> <p>9 generic field?</p> <p>10 A. Yes.</p> <p>11 Q. And you understood that at the time,</p> <p>12 right?</p> <p>13 A. I quite honestly didn't go that far.</p> <p>14 Q. Okay. Well, let's talk -- let's talk</p> <p>15 a little bit more about that in a second.</p> <p>16 Going through CIGNA 0111, you can see</p> <p>17 there's -- there's another listing of ipratropium</p> <p>18 bromide from Allscripts manufacturer, and that</p> <p>19 has a generic yes in that field indicator. Do</p> <p>20 you see that?</p> <p>21 A. Yes.</p> <p>22 Q. So it's -- Red Book is telling you</p>	<p style="text-align: right;">84</p> <p>1 package sizes, but, again, the generic field is</p> <p>2 telling you that that's a generic product,</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. Then if you turn to Page 8 and 9 of</p> <p>6 this October 2000 printout, which is CIGNA 0118</p> <p>7 and CIGNA 0119, you can see that the three</p> <p>8 Novaplus products are listed on the Red Book CD,</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And -- and the way these are</p> <p>12 listed by product name, it has the generic</p> <p>13 chemical name, ipratropium bromide, it then has a</p> <p>14 dash, and the word Novaplus, correct?</p> <p>15 A. Yes.</p> <p>16 Q. All right. And there are three</p> <p>17 different NDC entries on Pages 8 and 9, and they</p> <p>18 refer to different package sizes, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And for all three of these NDCs, the</p> <p>21 Red Book CD-ROM is telling you that these are</p> <p>22 also generic products, correct?</p>
<p style="text-align: right;">83</p> <p>1 that it considers the Allscripts ipratropium</p> <p>2 bromide to be a generic drug, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Then if you continue to flip through</p> <p>5 these next few pages, there's listings you'll see</p> <p>6 for Alparma ipratropium bromide, which is also</p> <p>7 called ipratropium bromide, and Dey's on Page 3</p> <p>8 of the Red Book printout.</p> <p>9 And if you continue on where there are</p> <p>10 some other NDCs and you get to Roxane's</p> <p>11 ipratropium bromide at the bottom of Page 5 of</p> <p>12 this October 2000 Red Book CD, do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. And there the product name is</p> <p>15 ipratropium bromide, the manufacturer is Roxane,</p> <p>16 and on the top of Page 6, Red Book, again, is</p> <p>17 telling you that this is a generic product,</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And it's the same for the other</p> <p>21 Roxane label ipratropium bromides, which are</p> <p>22 listed on Page 6. They're both in different</p>	<p style="text-align: right;">85</p> <p>1 A. Yes.</p> <p>2 Q. And it's telling you that because in</p> <p>3 the specific generic field it has a Y for yes for</p> <p>4 all three NDCs; isn't that right?</p> <p>5 A. Yes.</p> <p>6 Q. Now, did you take that information</p> <p>7 into account when you were classifying a Novaplus</p> <p>8 product in the Cigna arrays?</p> <p>9 A. No.</p> <p>10 Q. Can you explain why you didn't take</p> <p>11 that information into account?</p> <p>12 A. I was looking specifically at the name</p> <p>13 of the drug, the name of the drug being different</p> <p>14 than the generic name, so I considered it a brand</p> <p>15 name.</p> <p>16 Q. Okay. So the presence of the term</p> <p>17 Novaplus preceded by a dash would lead you to</p> <p>18 believe that it was a brand name versus a generic</p> <p>19 name?</p> <p>20 A. Yes.</p> <p>21 Q. And -- and just to be clear about the</p> <p>22 testimony we talked about earlier, you're</p>

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23 (Pages 86 to 89)

<p style="text-align: right;">86</p> <p>1 assuming that that was the decision that you made</p> <p>2 with respect to these drugs based upon the policy</p> <p>3 that Cigna had at the time; is that fair to say?</p> <p>4 MR. FAUCI: Object to form.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. And as -- as you sit here today, you</p> <p>8 don't have a specific recollection of exactly why</p> <p>9 you classified these particular Novaplast products</p> <p>10 here on Pages 8 and 9 as brands in the array?</p> <p>11 MR. FAUCI: Object to the form.</p> <p>12 THE WITNESS: I still recollect that I</p> <p>13 classified them as brand because the name is</p> <p>14 different. So my instruction is still if the</p> <p>15 name of the product is different than the generic</p> <p>16 name of the drug, then I consider it a brand.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. Yeah. And I -- I understand that that</p> <p>19 was your policy, correct? That was the policy</p> <p>20 that you understood that you implemented during</p> <p>21 this time, right?</p> <p>22 A. Yes.</p>	<p style="text-align: right;">88</p> <p>1 would say, yes, they're mine.</p> <p>2 Q. And -- and you would have circled them</p> <p>3 at the time that you had printed this out; is</p> <p>4 that correct?</p> <p>5 A. Yes.</p> <p>6 Q. Explain to me what the procedure was</p> <p>7 in terms of how these printouts were generated.</p> <p>8 A. There really wasn't a procedure. I</p> <p>9 printed them for my own reference in the event</p> <p>10 that I had to go back and look at the array. I</p> <p>11 would have the documentation since the CD</p> <p>12 wouldn't be available.</p> <p>13 Q. All right. So is it fair to say that</p> <p>14 all the printouts that we have that are attach --</p> <p>15 from the Red Book CD-ROM that are attached to the</p> <p>16 back of these arrays were printed on or about the</p> <p>17 time you were constructing the array that's --</p> <p>18 precedes the printout?</p> <p>19 A. Yes.</p> <p>20 Q. And then you kept these in your files</p> <p>21 over all these years?</p> <p>22 A. Yes.</p>
<p style="text-align: right;">87</p> <p>1 Q. My question is a little bit different.</p> <p>2 My question is, do you have a specific</p> <p>3 recollection about the actual decision that you</p> <p>4 made with respect to this particular drug at the</p> <p>5 time it first was put into a Cigna array?</p> <p>6 A. On here, I circled the Novaplast, so</p> <p>7 that's where I was thinking I needed to consider</p> <p>8 it -- or check on it.</p> <p>9 Q. Okay.</p> <p>10 A. But other than that, no, I'm -- I'm</p> <p>11 still thinking it's -- it's a brand name.</p> <p>12 Q. Now, looking at Pages 8 and 9 of this</p> <p>13 printout, what you're referring to are some</p> <p>14 underlinings under the word Novaplast and some</p> <p>15 circles around the term on this particular</p> <p>16 printout; is that right?</p> <p>17 A. Yes.</p> <p>18 Q. Can you identify those markings? Are</p> <p>19 they your pen marks?</p> <p>20 A. I believe that they are, yes.</p> <p>21 Q. You're not sure one way or the other?</p> <p>22 A. I -- because the array is mine, I</p>	<p style="text-align: right;">89</p> <p>1 Q. Now, why did you circle the single</p> <p>2 dose vial, which is the acronym SDV, five-by-five</p> <p>3 protecta-pack? Why would you circle that?</p> <p>4 A. I honestly don't know at this</p> <p>5 particular time. I had a question on it at that</p> <p>6 time. And I can't tell whether I was circling</p> <p>7 the single dose vial, protecta-pack, or the --</p> <p>8 whether it was the single dose vial or the fact</p> <p>9 that it was protecta-pack.</p> <p>10 I didn't know if the protecta-pack was</p> <p>11 like the Carpujects or something like that, I</p> <p>12 think is what I was looking at to go back and</p> <p>13 check, but I honestly don't know.</p> <p>14 Q. Okay. But there's no doubt that you</p> <p>15 were looking specifically at these detailed</p> <p>16 product information printouts from the Red Book</p> <p>17 CD-ROM because you actually circled certain</p> <p>18 segments of the hard copy on this, right?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And, therefore, you would have</p> <p>21 -- you would have definitely seen that Red Book</p> <p>22 had classified it as a generic drug, right?</p>

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24 (Pages 90 to 93)

<p style="text-align: right;">90</p> <p>1 A. I didn't look at that field.</p> <p>2 Q. So you would print this out, but you</p> <p>3 would stop reading at a point earlier on this</p> <p>4 printout?</p> <p>5 A. I would only look at the fields that I</p> <p>6 needed.</p> <p>7 Q. And what were those fields?</p> <p>8 A. I would be looking at the product</p> <p>9 name, the Orange Book description, additional</p> <p>10 description, generic name.</p> <p>11 Q. Well, what about the Orange Book code,</p> <p>12 what would you look at for that?</p> <p>13 A. There are certain Orange Book codes</p> <p>14 that we had to exclude from the array.</p> <p>15 Q. Which ones were those?</p> <p>16 A. I do not remember.</p> <p>17 Q. Do you know what the Orange Book code</p> <p>18 AN stands for?</p> <p>19 A. I do not. The Red Book has a listing.</p> <p>20 Q. It has a listing in -- in the cover --</p> <p>21 in the front cover of the Red Book?</p> <p>22 A. The hard copy, I believe so. And on</p>	<p style="text-align: right;">92</p> <p>1 field yes-or-no field, that's something you</p> <p>2 wouldn't pay attention to?</p> <p>3 A. I didn't go that far.</p> <p>4 Q. Just disregard that information</p> <p>5 entirely?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. If at the time you were</p> <p>8 classifying this drug as a brand you had seen</p> <p>9 that the Red Book, in fact, was telling you that</p> <p>10 it was a generic drug, would that have changed</p> <p>11 your classification decision?</p> <p>12 A. No.</p> <p>13 Q. And the reason for that is?</p> <p>14 A. Because the name of the drug has</p> <p>15 Novaplus in it. And per the CMS instructions, if</p> <p>16 the name of the drug is different than the</p> <p>17 generic name, I consider it to be a brand name.</p> <p>18 Q. It wouldn't matter what the Red Book</p> <p>19 compendia told you about the classification of</p> <p>20 the drug as a generic or brand, that information</p> <p>21 wouldn't be something you would consider?</p> <p>22 A. I wouldn't consider it.</p>
<p style="text-align: right;">91</p> <p>1 the CD, there is a drop-down box where you can</p> <p>2 find it.</p> <p>3 Q. And what would you do? You would look</p> <p>4 at the -- the Orange Book code and then refer</p> <p>5 over to the CD or to a hard copy to figure out</p> <p>6 what that Orange Book code was?</p> <p>7 A. No. There are certain Orange Book</p> <p>8 codes in some of the earlier instructions from</p> <p>9 CMS that were be -- to be excluded from the</p> <p>10 arrays, so I needed to check to see which.</p> <p>11 Q. Okay. Well, would it surprise you to</p> <p>12 know that the AN designation from the Orange Book</p> <p>13 code is in reference to a therapeutically</p> <p>14 equivalent solution, a generic drug? Would that</p> <p>15 surprise you?</p> <p>16 A. I honestly don't know what they are,</p> <p>17 so I wouldn't have looked. I mean, I don't -- it</p> <p>18 wouldn't surprise me because I don't know exactly</p> <p>19 what they are.</p> <p>20 Q. Okay. But you looked at the Orange</p> <p>21 Book code, but you -- you wouldn't look at the</p> <p>22 line that was seven lines down, in that generic</p>	<p style="text-align: right;">93</p> <p>1 Q. How about another compendia,</p> <p>2 FirstDataBank, for instance, if it told you it</p> <p>3 was a generic drug?</p> <p>4 A. I don't use FirstDataBank, so I would</p> <p>5 not have gone there.</p> <p>6 Q. I'm saying hypothetically speaking if</p> <p>7 you had known at the time you were classifying</p> <p>8 this drug as a brand that the Red Book compendia</p> <p>9 and FirstDataBank classified it as a generic</p> <p>10 drug, and it had a code from the Orange Book that</p> <p>11 indicated it was a generic drug, would that have</p> <p>12 made you consider whether it was a generic drug</p> <p>13 and not a brand?</p> <p>14 A. No.</p> <p>15 MR. FAUCI: Object to the form.</p> <p>16</p> <p>17</p> <p>18</p> <p>19 BY MR. GORTNER:</p> <p>20 Q. And you relied on the other</p> <p>21 information from the Red Book, right? You relied</p> <p>22 on the AWP's, correct?</p>

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25 (Pages 94 to 97)

<p style="text-align: right;">94</p> <p>1 A. Yes.</p> <p>2 Q. And you relied -- you relied on the</p> <p>3 product name being described accurately in the</p> <p>4 Red Book, right?</p> <p>5 A. Yes.</p> <p>6 Q. And you relied on its description of</p> <p>7 the route of administration, for instance?</p> <p>8 A. Yes.</p> <p>9 Q. So you relied on information about</p> <p>10 package size?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. So you consider it to be a</p> <p>13 reliable source of -- of information pertinent to</p> <p>14 your classification of this drug in the arrays,</p> <p>15 right?</p> <p>16 A. Yes.</p> <p>17 Q. Why -- why wouldn't you rely upon the</p> <p>18 generic indicator?</p> <p>19 A. I didn't ever go that far. I -- if</p> <p>20 the name was different, I followed the CMS</p> <p>21 instructions and considered it a brand.</p> <p>22 Q. Now, we -- we talked a moment earlier</p>	<p style="text-align: right;">96</p> <p>1 THE WITNESS: That was -- yes, I looked</p> <p>2 at the CD-ROM.</p> <p>3</p> <p>4</p> <p>5</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. So the answer is, that's correct, that</p> <p>8 it was based upon how the product was described</p> <p>9 in the Red Book CD-ROM, correct?</p> <p>10 MR. FAUCI: Object to the form.</p> <p>11 THE WITNESS: Yes, I based it on how it</p> <p>12 was listed in the CD-ROM.</p> <p>13 BY MR. GORTNER:</p> <p>14 Q. Did you at any point compare how</p> <p>15 things were listed in the CD-ROM to how they were</p> <p>16 listed in the printed Red Book?</p> <p>17 A. No.</p> <p>18 Q. Did you do so for this particular</p> <p>19 product? The answer would be no, I assume, since</p> <p>20 you didn't do it for any product, right?</p> <p>21 A. Right.</p> <p>22 Q. Probably withdraw that question.</p>
<p style="text-align: right;">95</p> <p>1 that looking at the annual hard copy Red Book</p> <p>2 printout, this same rule that you're referring to</p> <p>3 as the HCFA rule would have led you to classify</p> <p>4 the product as a generic, correct?</p> <p>5 A. Yes.</p> <p>6 Q. All right. So the classification of</p> <p>7 the product as a generic or a brand in your</p> <p>8 arrays depended on whether you were looking at</p> <p>9 the Red Book CD-ROM versus the Red Book hard copy</p> <p>10 version; is that correct?</p> <p>11 MR. FAUCI: Object to the form.</p> <p>12 THE WITNESS: I would say yes because</p> <p>13 it's listed differently in both. The hard copy</p> <p>14 did not say Novaplus. It only said ipratropium</p> <p>15 bromide. The CD says Ipratropium</p> <p>16 Bromide-Novaplus. The names are different, so I</p> <p>17 classified it based on how the name was listed.</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. Right. But the reason you classified</p> <p>20 it as a brand drug was because you were looking</p> <p>21 at the Red Book CD-ROM, correct?</p> <p>22 MR. FAUCI: Object to the form.</p>	<p style="text-align: right;">97</p> <p>1 Now, how about if the product was</p> <p>2 listed ipratropium bromide-Roxane instead of</p> <p>3 Novaplus?</p> <p>4 MR. FAUCI: Object to the form.</p> <p>5 BY MR. GORTNER:</p> <p>6 Q. How would you have classified that</p> <p>7 drug?</p> <p>8 A. I would have classified it as a brand</p> <p>9 name.</p> <p>10 Q. And if the product were listed as</p> <p>11 ipratropium bromide-CVS?</p> <p>12 A. I would have classified it as a brand</p> <p>13 name.</p> <p>14 Q. And what are some other large retail</p> <p>15 pharmacy chains in the Nashville area? Do you</p> <p>16 have Walgreens down here?</p> <p>17 A. We do.</p> <p>18 Q. And you're familiar that Walgreens has</p> <p>19 a series of drugs that it -- it lists under a</p> <p>20 Walgreens name? For instance, have you seen</p> <p>21 Walgreens ibuprofen, for instance?</p> <p>22 A. I don't use Walgreens. I don't -- I'm</p>

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<p style="text-align: right;">98</p> <p>1 not familiar with it.</p> <p>2 Q. What pharmacy do you use?</p> <p>3 A. Actually I go through Cigna Tel-Drug.</p> <p>4 Q. That would make sense given a Cigna</p> <p>5 employee.</p> <p>6 Well, let's say that -- that the drug</p> <p>7 was listed as ipratropium bromide-Walgreens, for</p> <p>8 instance. How would you have classified the drug</p> <p>9 like that?</p> <p>10 A. If the drug -- if we're talking about</p> <p>11 it listed in the Red Book as, then I would</p> <p>12 classify it as a brand name.</p> <p>13 Q. It doesn't matter what comes after the</p> <p>14 dash, anything that's different than the words</p> <p>15 ipratropium bromide would lead you to classify</p> <p>16 the drug as a brand?</p> <p>17 A. Yes.</p> <p>18 MR. FAUCI: Objection to the form.</p> <p>19 BY MR. GORTNER:</p> <p>20 Q. So even if the title said Ipratropium</p> <p>21 Bromide-Novaplast and had a follow-up dash that</p> <p>22 said this is a generic drug in the full title,</p>	<p style="text-align: right;">100</p> <p>1 Q. Now, what's your understanding of what</p> <p>2 a proprietary name is?</p> <p>3 MR. FAUCI: Object to the form.</p> <p>4 THE WITNESS: I quite honestly don't</p> <p>5 have an understanding of proprietary.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. Okay. And do you have an</p> <p>8 understanding of what a trade name is?</p> <p>9 A. My understanding is that it's specific</p> <p>10 to one entity. I mean, it's -- I don't really</p> <p>11 know the difference between -- I mean, I think</p> <p>12 it's specific to one company only, and no one</p> <p>13 else can use that.</p> <p>14 Q. Do you have any understanding whether</p> <p>15 Novaplast is a trade name?</p> <p>16 MR. FAUCI: Object to the form.</p> <p>17 THE WITNESS: I -- I don't.</p> <p>18 BY MR. GORTNER:</p> <p>19 Q. You don't know one way or the other,</p> <p>20 right?</p> <p>21 A. Right.</p> <p>22 Q. Do you have any understanding whether</p>
<p style="text-align: right;">99</p> <p>1 you would still classify it as a brand, wouldn't</p> <p>2 you?</p> <p>3 MR. FAUCI: Object to the form.</p> <p>4 THE WITNESS: I have never seen one</p> <p>5 that way, so I might at this particular point ask</p> <p>6 for classification from CMS.</p> <p>7 BY MR. GORTNER:</p> <p>8 Q. Okay. So there's some point where you</p> <p>9 would seek some information from somebody else to</p> <p>10 try to clarify whether that drug should be a</p> <p>11 generic or brand, right?</p> <p>12 A. Yes.</p> <p>13 Q. But you'd agree with me that even</p> <p>14 under that hypothetical scenario, technically</p> <p>15 that -- under your -- meets your understanding of</p> <p>16 the HCFA rules of being a brand, right?</p> <p>17 A. Yes.</p> <p>18 Q. Because that title, even if it says</p> <p>19 this is a generic drug, those are words that are</p> <p>20 different than exclusively the generic name of</p> <p>21 the drug, right?</p> <p>22 A. Yes.</p>	<p style="text-align: right;">101</p> <p>1 Novaplast is a proprietary name?</p> <p>2 A. No, I don't.</p> <p>3 Q. You don't know one way or the other?</p> <p>4 Now, with respect to the Novaplast</p> <p>5 drugs, were you familiar with that Novaplast</p> <p>6 designation?</p> <p>7 A. I have seen it in the array. But</p> <p>8 familiar with it, no. I just put it into the</p> <p>9 arrays.</p> <p>10 Q. So you didn't know what the Novaplast</p> <p>11 meant?</p> <p>12 A. Correct.</p> <p>13 Q. You didn't know that these were drugs</p> <p>14 that were being sold exclusively to Novation's</p> <p>15 GPO members?</p> <p>16 A. No.</p> <p>17 Q. But you knew that it was the same</p> <p>18 manufacturer, Roxane, as -- as the other</p> <p>19 ipratropium bromide that was listed on Pages 5</p> <p>20 and 6 of this Red Book CD, right?</p> <p>21 A. Same manufacturer, yes.</p> <p>22 Q. And you can see that the same -- the</p>

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<p style="text-align: right;">102</p> <p>1 same manufacturer had named both products with</p> <p>2 the terms ipratropium bromide in the title,</p> <p>3 right?</p> <p>4 A. Yes.</p> <p>5 Q. And with respect to the Roxane label</p> <p>6 ipratropium bromide, there was no doubt in your</p> <p>7 mind that that was a generic product at all</p> <p>8 times, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And you never stopped to think about</p> <p>11 the fact that Roxane had a generic product with</p> <p>12 the title ipratropium bromide in it and another</p> <p>13 product with the addition of Novaplus and that</p> <p>14 those two products were likely to be generics?</p> <p>15 MR. FAUCI: Object to the form.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. How about the fact that the AWP's were</p> <p>19 identical for the respective package sizes</p> <p>20 between the Roxane label and the Novaplus label</p> <p>21 ipratropium bromide?</p> <p>22 A. No.</p>	<p style="text-align: right;">104</p> <p>1 three-year plus period that they were in the</p> <p>2 arrays?</p> <p>3 A. No.</p> <p>4 Q. And were you aware that the Palmetto</p> <p>5 DMERC for one quarter isn't sure whether they</p> <p>6 classified that product as a generic or a brand</p> <p>7 in its array?</p> <p>8 A. No.</p> <p>9 Q. And had you known that DMERC-A was</p> <p>10 classifying this product as a generic about that</p> <p>11 time would that have caused you to reconsider</p> <p>12 your classification of it as a brand?</p> <p>13 A. We might have discussed it on the</p> <p>14 call. We would have still said we thought it</p> <p>15 should have been brand because of the name, but</p> <p>16 there could have been discussion.</p> <p>17 Q. Now, are you familiar with -- with the</p> <p>18 process by which the Cigna Part B carrier</p> <p>19 constructs arrays for non-DMERC drugs?</p> <p>20 A. No.</p> <p>21 Q. Where -- where is -- where is the</p> <p>22 Cigna Part B?</p>
<p style="text-align: right;">103</p> <p>1 Q. You didn't pay attention to that?</p> <p>2 A. No.</p> <p>3 Q. Can you think of any instance where</p> <p>4 you were unsure whether a product should be</p> <p>5 classified as a generic or a brand?</p> <p>6 A. I cannot.</p> <p>7 Q. Do you think there was any such</p> <p>8 instance where there was confusion in your mind</p> <p>9 about whether a product should be a generic or a</p> <p>10 brand?</p> <p>11 MR. FAUCI: Object to the form.</p> <p>12 THE WITNESS: I honestly can't remember</p> <p>13 specifics. I can't say that during that entire</p> <p>14 time that there might have been some</p> <p>15 conversations for -- on the different calls with</p> <p>16 the DMERCs, whether we classify, you know, in the</p> <p>17 brand or the generics when we were discussing the</p> <p>18 arrays and we came out with different amounts.</p> <p>19 BY MR. GORTNER:</p> <p>20 Q. Are you aware that DMERC-A classified</p> <p>21 these same Ipratropium Bromide-Novaplus products</p> <p>22 as generic products in their arrays the entire</p>	<p style="text-align: right;">105</p> <p>1 A. Cigna Part B is in the same building.</p> <p>2 They're on different floors than I am.</p> <p>3 Q. So they're located in the same</p> <p>4 building as you?</p> <p>5 A. Yes.</p> <p>6 Q. Do you ever interact with the staff</p> <p>7 that construct arrays for Cigna Part B?</p> <p>8 A. As far as developing the arrays?</p> <p>9 Q. Yes.</p> <p>10 A. The only interaction I've had is</p> <p>11 helping them -- or they looked at some of our</p> <p>12 spreadsheets initially when they were going from</p> <p>13 hard copy to spreadsheets.</p> <p>14 Q. Okay.</p> <p>15 A. And then, of course, with the CD when</p> <p>16 we went to multiuser, we have to -- the -- the CD</p> <p>17 is shared between the two contracts, so we</p> <p>18 interact with getting the CD tested and loaded.</p> <p>19 Q. But you never interact with them in</p> <p>20 terms of how they classify products as generics</p> <p>21 or brands, for instance?</p> <p>22 A. No.</p>

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<p style="text-align: right;">106</p> <p>1 Q. Now, as far as you know, isn't Part B 2 operating under the same criteria for classifying 3 generics and brands as the DMERCs are? 4 A. I don't know. 5 Q. But do you see any reason based on 6 your awareness of the HCFA transmittal and the 7 Medicare drug pricing procedure documents why 8 Cigna's Medicare Part B carrier should be 9 classifying drugs differently than you as the 10 DMERC should? 11 A. I don't have their instructions, so I 12 can't say. We had different regional contracts. 13 We look at drugs differently because we have 14 different coverage criteria. So I cannot say how 15 they actually classify and if they have the same 16 instructions. 17 Q. So it's possible that they're using 18 different criteria for classifying drugs than you 19 are? 20 A. Yes. 21 Q. So maybe they're not looking to the -- 22 to the product name to see whether it's a gen- --</p>	<p style="text-align: right;">108</p> <p>1 applied to the Part B but did not apply to the 2 DMERCs. 3 Q. Let's take a look at this HCFA 4 transmittal that you've been referring to. Maybe 5 that will help clarify this issue. I'm going to 6 hand you what's been previously marked as Abbott 7 529. We're going to go ahead and mark it as 8 Roxane 263. 9 (Marked Exhibit Roxane 263.) 10 BY MR. GORTNER: 11 Q. Here you go, Ms. Helton. And this is 12 Transmittal No. AB-98-76 dated December 1998, and 13 it's a program memorandum to intermediaries and 14 carriers. Do you see this? 15 A. Yes. 16 Q. And I'll draw your attention to the 17 middle of the page under calculation of the AWP 18 No. 2, HCFA writes in the second sentence, "A 19 brand name product is defined as a product that 20 is marketed under a label name that is other than 21 the generic chemical name for the drug or 22 biological."</p>
<p style="text-align: right;">107</p> <p>1 whether it's a generic chemical name or something 2 other than generic chemical name to determine 3 whether it's a brand; is that right? 4 A. I don't have their instructions, so I 5 -- I would say that they could have different 6 instructions. I just don't know. 7 Q. But you know, don't you, that they 8 have classified other drugs that have the label 9 Novaplus in it as a generic and not a brand, 10 right? 11 A. I did get some of their -- or looked 12 at some of their arrays for this case. Those 13 were some that were sent to me, and, yes, I did 14 see that they arrayed them as generics. 15 Q. Okay. So even within Cigna, there 16 wasn't consistency between the DMERC 17 classification of a drug with a Novaplus in its 18 title and the Part B classification of the drug 19 with Novaplus in its title, right? 20 A. Yes, but they're different contracts 21 with different -- possibly different 22 instructions. For example, single drug pricer</p>	<p style="text-align: right;">109</p> <p>1 Do you see that? 2 A. Yes. 3 Q. And that's the -- the criteria that 4 you've been referring to that you apply to 5 classifying drugs as generics or brands, right? 6 A. Yes. 7 Q. And this program memorandum was sent 8 to all Medicare carriers, right? 9 A. I cannot say whether it was or. It -- 10 I mean, it appears at the top. All I know is 11 that I received it. 12 Q. Do you have any reason to believe that 13 -- that this program memorandum and the statement 14 within it here with respect to brand name 15 products wouldn't apply to Cigna's Part B 16 carrier? 17 A. I don't know if they get separate 18 instructions or not. 19 Q. Well, in terms of establishing the 20 payment methodology for Part B drugs, is it your 21 understanding that Cigna's Part B drugs would be 22 paid under a different methodology than the</p>

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<p style="text-align: right;">110</p> <p>1 median AWP of generics or the brand AWP if it 2 were lower? 3 A. I don't know what methodology they 4 used. I -- I wasn't -- when these instructions 5 came out, I wasn't in the loop of who they were 6 sent to. I only got them after the fact, so I 7 can only say that I saw the instruction. 8 Q. But you've been using that -- that 9 instruction throughout the time period 2001 to 10 2004, right? 11 A. Yes. 12 Q. Let's take a look at what I'll mark as 13 Roxane Exhibit 264. 14 (Marked Exhibit Roxane 264.) 15 BY MR. GORTNER: 16 Q. And I believe this is a document you 17 may have seen before. It is a -- an array from 18 the Cigna Medicare Part B carrier with respect to 19 a drug called doxorubicin hydrochloride. Have 20 you seen this document before, Ms. Helton? 21 A. I'm not sure if this is one that was 22 sent to me to look at or not.</p>	<p style="text-align: right;">112</p> <p>1 A. Yes. 2 Q. Okay. And then above, there's a 3 listing of products that appear to be in the 4 generic portion of the array, correct? 5 A. Yes. 6 Q. And included in that generic portion 7 are doxorubicin Novaplus with a parens for 8 Bedford, right? 9 A. Yes. 10 Q. And -- and that would indicate to you 11 that the Part B carrier had classified it -- the 12 drug name doxorubicin Novaplus as a generic? 13 A. Yes. 14 Q. And had you been looking at that same 15 drug with that same name, you would have 16 classified it as a brand; isn't that right? 17 A. That is correct. 18 Q. And you don't know of any reason, 19 though, do you, why one drug should be classified 20 as a brand in a DMERC scenario versus a generic 21 in a Part B scenario, do you? 22 A. I don't have Part B's instructions,</p>
<p style="text-align: right;">111</p> <p>1 Q. Okay. I'll represent to you that -- 2 the document as I described it a moment ago. And 3 as you can see at the top in the pricing sheet, 4 it says, "Doxorubicin hydrochloride HCL," and 5 then it has a reference specifically to Novaplus 6 in the title. Do you see that? 7 A. Yes. 8 Q. And the document is dated May 13th, 9 2002, right? 10 A. Yes. 11 Q. And it looks like it's the 2002 12 pricing for the third quarter, correct? 13 A. Yes. 14 Q. And if you look at the bottom of the 15 -- of the array, you can see that there's a 16 series of entries for what says brand Rx, and 17 those appear to be entries for products that are 18 in the brand portion of the array. Do you see 19 that? 20 A. Yes. 21 Q. It begins with the term Adriamycin. Do 22 you see that?</p>	<p style="text-align: right;">113</p> <p>1 so, no, I'm not aware. 2 Q. But depending upon the classification 3 of the drug as a generic or a brand, I mean, that 4 could significantly change the fee payment amount 5 that you set, right? 6 A. Yes. 7 Q. If it turned out that the brand AWP 8 was significantly lower than the median generic, 9 then that could have an impact theoretically, 10 right? 11 A. Okay. Could you repeat that? 12 MR. GORTNER: That's all right. I'll 13 withdraw the question. That's fine. 14 Why don't we take a quick break, and I 15 can see how much more time, if any, I need. Okay? 16 Thanks. 17 THE VIDEOGRAPHER: Going off the 18 record, time is 11:21. 19 (Brief recess observed.) 20 THE VIDEOGRAPHER: Back on the record. 21 Time is 11:30. 22</p>

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<p style="text-align: right;">114</p> <p>1 BY MR. GORTNER:</p> <p>2 Q. Ms. Helton, going back to your</p> <p>3 classification of Novaplus Ipratropium Bromide as</p> <p>4 a brand, was it the case that when you made your</p> <p>5 initial classification it remained the same at</p> <p>6 each period where you updated the array? In</p> <p>7 other words, you wouldn't go back and reconsider</p> <p>8 the classification of the product each quarter?</p> <p>9 A. Correct. If the name didn't change --</p> <p>10 remained the same, I wouldn't have reclassified</p> <p>11 it.</p> <p>12 Q. Okay. So what probably happened here</p> <p>13 was the first time that the product showed up in</p> <p>14 the Red Book and you determined that it should be</p> <p>15 put into the array as a brand, that -- that</p> <p>16 decision wasn't evaluate -- reevaluated each --</p> <p>17 each quarter, right?</p> <p>18 A. As long as nothing changed on the --</p> <p>19 on the name, correct.</p> <p>20 Q. Well, was the process such that the --</p> <p>21 that the -- the actual arrays would be resaved or</p> <p>22 reused from quarter to quarter? In other words,</p>	<p style="text-align: right;">116</p> <p>1 versus CD-ROM, for instance?</p> <p>2 A. No.</p> <p>3 Q. So a manufacturer like Roxane, for</p> <p>4 instance, wouldn't know that you were looking to</p> <p>5 the Red Book CD-ROM versus the annual printed Red</p> <p>6 Book, for instance, to set up your pricing</p> <p>7 arrays?</p> <p>8 A. No.</p> <p>9 MR. FAUCI: Object to the form.</p> <p>10 BY MR. GORTNER:</p> <p>11 Q. And Roxane wouldn't know, therefore,</p> <p>12 that you were classifying Ipratropium</p> <p>13 Bromide-Novaplus as a brand based upon the Red</p> <p>14 Book CD-ROM, correct?</p> <p>15 A. Correct.</p> <p>16 MR. FAUCI: Object to the form.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. And Roxane wouldn't know that you had</p> <p>19 put the Ipratropium Bromide-Novaplus product into</p> <p>20 your brand versus generic array, correct?</p> <p>21 A. Correct.</p> <p>22 Q. If you had called Roxane and asked</p>
<p style="text-align: right;">115</p> <p>1 what I mean to say is that the first time that</p> <p>2 Novaplus showed up as a brand in the array you</p> <p>3 constructed, would the next quarter of arrays</p> <p>4 simply you opening up that file again and</p> <p>5 importing any new drugs that came in but</p> <p>6 otherwise leaving the drugs that were in there</p> <p>7 unaltered?</p> <p>8 A. Yes, we -- we would verify the old</p> <p>9 drugs, that there were no changes in AWP,</p> <p>10 packaging. And if they remained the same, then</p> <p>11 we didn't make changes to them; we added the new</p> <p>12 ones that came in.</p> <p>13 Q. Okay. But as long as that name was</p> <p>14 the same, it remained a brand in your arrays</p> <p>15 across time?</p> <p>16 A. Yes.</p> <p>17 Q. Now, with respect to Cigna's decision</p> <p>18 in concert with other DMERCs to look principally</p> <p>19 to Red Book's CD-ROMs for pricing information,</p> <p>20 would anyone outside of the DMERCs have a way of</p> <p>21 knowing which particular Red Book you were</p> <p>22 looking at to make your pricing arrays, printed</p>	<p style="text-align: right;">117</p> <p>1 them whether they considered Ipratropium</p> <p>2 Bromide-Novaplus product to be a generic or brand</p> <p>3 and they had told you that they always believed</p> <p>4 it was a generic, would that have affected your</p> <p>5 classification decision?</p> <p>6 A. I wouldn't have the need to call them.</p> <p>7 I'm going by my instructions, so I wouldn't have</p> <p>8 contacted them for that information.</p> <p>9 Q. My question is a little different. I'm</p> <p>10 not asking you just to assume that you did, in</p> <p>11 fact, contact Roxane about Ipratropium</p> <p>12 Bromide-Novaplus and a Roxane representative</p> <p>13 informed you that they always considered this to</p> <p>14 be a generic and not a brand product. Would that</p> <p>15 have affected your classification decision?</p> <p>16 MR. FAUCI: Object to the form.</p> <p>17 THE WITNESS: I would say no, because</p> <p>18 based on the instructions, the name being</p> <p>19 different makes it a brand.</p> <p>20 BY MR. GORTNER:</p> <p>21 Q. Now, with respect to the name being</p> <p>22 different, I mean, the actual phrase that you've</p>

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<p style="text-align: right;">118</p> <p>1 been referring to is if it's a -- a product name 2 that is other than a generic chemical name; is 3 that correct? 4 A. Let's see. "Brand name product is 5 defined as a product that is marketed under a 6 label name that is other than the generic 7 chemical name for the drug or biological." 8 Q. And that's the -- that's the rule that 9 you testify you were using for classifying the 10 Novaplus product? 11 A. Yes. 12 Q. Would you agree with me that the name 13 Ipratropium Bromide-Novaplus doesn't fall clearly 14 within that particular rule? 15 MR. FAUCI: Object to the form. 16 THE WITNESS: No, I actually think it 17 does. 18 BY MR. GORTNER: 19 Q. Were you familiar during the course of 20 your work with Cigna about normal industry naming 21 conventions for generic versus brand drugs? 22 MR. FAUCI: Object to the form.</p>	<p style="text-align: right;">120</p> <p>1 brands. So that's how I consider them brands. 2 But as far as how the pharmaceutical 3 companies do the naming, no, I'm not familiar 4 with it. 5 BY MR. GORTNER: 6 Q. And -- and the concept that every 7 single generic drug for ipratropium bromide that 8 you placed into your generic array had the 9 generic chemical name ipratropium bromide in its 10 title, that wasn't a factor that you considered 11 in determining whether a drug that had 12 ipratropium bromide in its title plus the term 13 Novaplus might be at least in an ambiguous 14 position with respect to that rule? 15 MR. FAUCI: Object to the form. 16 THE WITNESS: I don't really understand 17 the complete question. I mean -- 18 BY MR. GORTNER: 19 Q. Let's see if I can simplify it. I 20 mean, we have a situation here where every single 21 drug that you classified as a generic in your 22 array was called ipratropium bromide, which was</p>
<p style="text-align: right;">119</p> <p>1 THE WITNESS: Not naming conventions, 2 no. 3 BY MR. GORTNER: 4 Q. During the course of preparing the 5 arrays, you weren't aware that brand drugs are 6 typically given a -- a name that doesn't refer to 7 the generic chemical name like Atrovent, for 8 instance, or Valium? 9 A. No, I only follow the instructions 10 that I have. 11 Q. Okay. So during the process of 12 implementing the instructions, you weren't 13 informed by any understanding as to how the 14 pharmaceutical industry typically names brand 15 versus generic drugs? 16 MR. FAUCI: Object to the form. 17 THE WITNESS: I don't have any input 18 with the pharmaceutical industry, so I'm only 19 looking at it from the standpoint of what my 20 instructions are and what's in the source that 21 I'm looking at. And I can see that certain 22 products, you know, that had different names are</p>	<p style="text-align: right;">121</p> <p>1 the generic chemical name, correct? 2 A. Yes. 3 Q. Right. And you have a situation where 4 here comes another drug that's called Atrovent, 5 something completely different, and you put that 6 in a brand, right? 7 A. Yes. 8 Q. Then there's a third situation where 9 you have a drug that has the term ipratropium 10 bromide in its title, which is the generic 11 chemical name, right? 12 A. Yes. 13 Q. Which is the basis by which you 14 classified the other drugs with those two words, 15 ipratropium bromide, as generics, correct? 16 A. Yes. 17 Q. And then -- that has the addition of a 18 dash and the term Novaplus, correct? 19 A. Yes. 20 Q. My question is, under that third 21 scenario where you have both the generic chemical 22 name and an additional name, wouldn't you agree</p>

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32 (Pages 122 to 125)

<p style="text-align: right;">122</p> <p>1 with me that there's a reasonable interpretation</p> <p>2 that a drug that's named like that falls</p> <p>3 somewhere in between?</p> <p>4 A. No.</p> <p>5 MR. FAUCI: Object to the form.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. And the reason is because any term in</p> <p>8 addition to the generic chemical name in your</p> <p>9 view automatically makes it a brand; is that</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 Q. Now, did you assume throughout this</p> <p>13 time that the other DMERCs were applying the same</p> <p>14 type of rule that you were with respect to</p> <p>15 classifying drugs such as Ipratropium</p> <p>16 Bromide-Novaplas as a brand or a generic?</p> <p>17 A. Yes.</p> <p>18 Q. Now, what's your explanation if the</p> <p>19 rule was clear as you contend how DMERC-A</p> <p>20 classified the exact same drug with the exact</p> <p>21 same name as a generic for over three years?</p> <p>22 A. I don't have an explanation.</p>	<p style="text-align: right;">124</p> <p>1 A. Correct.</p> <p>2 Q. Did you know that the Administar DMERC</p> <p>3 classified the Roxane labeled ipratropium bromide</p> <p>4 product as a generic for over a year?</p> <p>5 A. No.</p> <p>6 Q. You weren't aware of that either?</p> <p>7 A. No.</p> <p>8 Q. And that was a product that you</p> <p>9 classified as a generic the entire time it was in</p> <p>10 the Cigna arrays; isn't that correct? I'll</p> <p>11 represent to you that you did.</p> <p>12 A. Okay.</p> <p>13 Q. Okay. And that decision whether to</p> <p>14 put Roxane labeled ipratropium bromide in a</p> <p>15 generic array for Cigna at least was based on</p> <p>16 this same HCFA rule that we've been talking about</p> <p>17 about whether it's a generic chemical name or</p> <p>18 not, right?</p> <p>19 A. Yes.</p> <p>20 Q. And you believe that Administar was</p> <p>21 applying that -- that rule as well?</p> <p>22 A. I assumed they were.</p>
<p style="text-align: right;">123</p> <p>1 Q. But wouldn't that suggest to you that,</p> <p>2 therefore, the rule, if, in fact, DMERC-A was</p> <p>3 applying it, is not as clear as you would suggest</p> <p>4 --</p> <p>5 MR. FAUCI: Object.</p> <p>6 BY MR. GORTNER:</p> <p>7 Q. -- with respect to this product?</p> <p>8 MR. FAUCI: Object to the form.</p> <p>9 THE WITNESS: To me, the rule seems</p> <p>10 clear, so I can't speculate on what A did.</p> <p>11 BY MR. GORTNER:</p> <p>12 Q. Have you had sufficient interactions</p> <p>13 with DMERC-A representatives during this time</p> <p>14 period 2001 and 2004 to -- to determine whether</p> <p>15 you think they can perform their job duties</p> <p>16 competently?</p> <p>17 A. No.</p> <p>18 MR. FAUCI: Object to the form.</p> <p>19 BY MR. GORTNER:</p> <p>20 Q. It's the same for all the other</p> <p>21 DMERCs, you don't know whether they were doing</p> <p>22 their job competently or not?</p>	<p style="text-align: right;">125</p> <p>1 Q. And their application of that rule led</p> <p>2 them to misclassify the Roxane labeled product as</p> <p>3 a brand for over a year?</p> <p>4 MR. FAUCI: Object to the form.</p> <p>5 BY MR. GORTNER:</p> <p>6 Q. Do you know that?</p> <p>7 A. I don't know actually how they</p> <p>8 classified it, so I don't know.</p> <p>9 Q. Does that additional piece of</p> <p>10 information, assuming it to be true, lead you to</p> <p>11 reconsider whether you believe that HCFA rule is</p> <p>12 clear with respect to Ipratropium</p> <p>13 Bromide-Novaplas?</p> <p>14 MR. FAUCI: Object to the form.</p> <p>15 THE WITNESS: To me, the rule seems</p> <p>16 clear.</p> <p>17 BY MR. GORTNER:</p> <p>18 Q. I wanted to go back quickly to your</p> <p>19 declaration which we marked earlier today as</p> <p>20 Roxane 260, I believe. If you could turn to Page</p> <p>21 13 in particular of your declaration.</p> <p>22 In Paragraph 31 of the declaration, you</p>

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33 (Pages 126 to 129)

<p style="text-align: right;">126</p> <p>1 mentioned, "During the period 2001, quarter 2, to 2 2003, quarter 4, when Roxane's Novaplus were in 3 the arrays, Cigna generally used the quarterly 4 CD-ROM as a source of information." 5 Do you see that in Paragraph 31? 6 A. Yes. 7 Q. Now, you don't mention the use of the 8 -- the monthly Red Book updates during this time 9 period. But you were using those as well, 10 weren't you? 11 A. We were checking those to see if there 12 were any additions that weren't copied in the CD. 13 Q. Okay. So you were using both the 14 CD-ROM and the paper versions of the Red Book 15 during this time as well, correct? 16 A. The monthly, yes. 17 Q. The answer is yes? 18 A. Yes. 19 MR. GORTNER: I don't have any further 20 questions. Thank you so much for your time. 21 MR. FAUCI: Marisa, do you have any 22 questions?</p>	<p style="text-align: right;">128</p> <p>1 So we would look at any Red Books that 2 we would get in between that time, such as 3 November or December, to see if we could pick up 4 any additional changes that we needed to. 5 Generally we would refer to those, and 6 Red Book had changes in red print, so we would 7 only be looking at the ones that were in red 8 print. 9 Q. Do you know if you ever looked to the 10 monthly updates to the Red Book in deciding how 11 to classify Ipratropium Bromide-Novaplus as a 12 brand or a generic? 13 A. No. 14 Q. No, you do not know; or, no, you 15 didn't? 16 A. No, we didn't. Sorry. 17 Q. Thank you. That was my fault. 18 Can you look back at Exhibit 263? I 19 believe this was the program memoranda. We've 20 talked at length about the language contained in 21 Paragraph 2 under the calculation of the AWP. Do 22 you see that?</p>
<p style="text-align: right;">127</p> <p>1 MS. LORENZO: No, I do not. Thank you. 2 MR. FAUCI: How much time do we have? 3 THE VIDEOGRAPHER: It looks like about 4 14 minutes. 5 MR. FAUCI: Let's try. 6 EXAMINATION 7 BY MR. FAUCI: 8 Q. Ms. Helton, I just have a very few 9 quick follow-up questions. 10 First, just in response to testimony 11 you just gave, you said that you were -- at the 12 time you were using the Red Book for Windows 13 program you were also using the monthly updates; 14 is that correct? 15 A. Yes. 16 Q. Can you explain how you used the 17 monthly updates for what purpose? 18 A. The quarterly Windows was a month 19 behind when we would be developing the fees. For 20 example, we would be using the October 2009 to 21 establish the -- or October 1999 to establish the 22 January 2000 fees.</p>	<p style="text-align: right;">129</p> <p>1 A. Yes. 2 Q. Can you read the last sentence of that 3 paragraph? 4 A. "A brand name product is defined as a 5 product that is marketed under a label name that 6 is other than the generic chemical name for the 7 drug or biological." 8 Q. Did you rely on this language in 9 making classification decisions? 10 A. Yes. 11 Q. Can you go to Exhibit 261, and I'll 12 direct your attention to the Page 368. Is this a 13 -- is this pages excerpted from the 2001 hard 14 copy version of the annual Red Book? 15 A. Yes. 16 Q. And you see that there's a section 17 related to ipratropium bromide? 18 A. Yes. 19 Q. Do you recall talking to Mr. Gortner 20 earlier about the Roxane products that are listed 21 in the second column? 22 A. Yes.</p>

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34 (Pages 130 to 133)

<p style="text-align: right;">130</p> <p>1 Q. And you gave some testimony that those</p> <p>2 products -- based on what you see here you would</p> <p>3 have classified those products -- all six of</p> <p>4 those products as generics; is that correct?</p> <p>5 A. Yes, that's --</p> <p>6 Q. Can you explain why you would have</p> <p>7 done so?</p> <p>8 A. Because they only list the name of the</p> <p>9 drug as ipratropium bromide.</p> <p>10 Q. If for the 8404 NDCs the product was</p> <p>11 listed as Ipratropium Bromide-Novaplus, how would</p> <p>12 you have classified them?</p> <p>13 A. A brand name.</p> <p>14 Q. Just going to very quickly -- we've</p> <p>15 been talking about the Red Book for Windows</p> <p>16 program, and I'd just like to ask a quick few</p> <p>17 questions.</p> <p>18 (Marked Exhibit US 265.)</p> <p>19 BY MR. FAUCI:</p> <p>20 Q. Do you recognize this, Ms. Helton?</p> <p>21 A. Yes.</p> <p>22 Q. What is it?</p>	<p style="text-align: right;">132</p> <p>1 Q. Is this -- is -- how you would have</p> <p>2 used this program is by typing in the drug you</p> <p>3 were looking to get information on into the</p> <p>4 search screen?</p> <p>5 A. Yes.</p> <p>6 Q. And if you had typed in ipratropium,</p> <p>7 is this what would have come up on the screen?</p> <p>8 A. Yes.</p> <p>9 Q. What would have happened if you</p> <p>10 clicked ipratropium, if you had hit enter or</p> <p>11 okay?</p> <p>12 A. On this particular one?</p> <p>13 Q. On this particular screen -- no, which</p> <p>14 of these would you have selected?</p> <p>15 A. I would have selected the lower case,</p> <p>16 the ipratropium bromide, because it would have</p> <p>17 pulled all of the ipratropium bromides into that</p> <p>18 and then hit okay.</p> <p>19 Q. And what would have happened then?</p> <p>20 A. Then it would have brought up a list</p> <p>21 of manufacturers for the different drugs.</p> <p>22 Q. And you would have used that list of</p>
<p style="text-align: right;">131</p> <p>1 A. It's the search database that comes up</p> <p>2 when you open -- enter Red Book.</p> <p>3 Q. Just for the record, I'll represent</p> <p>4 that I did a print screen from the -- a version</p> <p>5 of the Red Books for Windows. And you've</p> <p>6 identified this as the search database?</p> <p>7 A. Yes.</p> <p>8 Q. Is this the first screen that popped</p> <p>9 up when you looked at the Red Book for Windows?</p> <p>10 A. Yes.</p> <p>11 Q. You can put that aside.</p> <p>12 (Marked Exhibit US 266.)</p> <p>13 BY MR. FAUCI:</p> <p>14 Q. Do you recognize Exhibit 266, Ms.</p> <p>15 Helton?</p> <p>16 A. Yes.</p> <p>17 Q. What is this -- what does this appear</p> <p>18 to be?</p> <p>19 A. Once you type in the brand into the</p> <p>20 selection field, this is the array that you get</p> <p>21 that comes up with the word ipratropium. And it</p> <p>22 has an N capitalized in lowercase.</p>	<p style="text-align: right;">133</p> <p>1 manufacturers to -- how would you have used that</p> <p>2 list of manufacturers?</p> <p>3 A. I would have said select all, because</p> <p>4 I wanted to pull all manufacturers in, and then</p> <p>5 hit okay.</p> <p>6 Q. And can you explain what that would</p> <p>7 have done?</p> <p>8 A. It then brings up the detailed screen,</p> <p>9 which are some of these that we looked at the</p> <p>10 prints.</p> <p>11 Q. On Exhibit 262?</p> <p>12 A. Yes -- well, actually, it brings up</p> <p>13 another screen before the ones on 262 where it</p> <p>14 lists all of the -- it has -- it's the -- the</p> <p>15 product information screen comes up, and it lists</p> <p>16 all of the manufacturers and the products that</p> <p>17 meet that ipratropium bromide generic</p> <p>18 description.</p> <p>19 And then I go in and make my selections</p> <p>20 for the code that I'm trying to process as to</p> <p>21 what actually I'm going to pull into the array</p> <p>22 based on the strength and the type of the drug.</p>

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35 (Pages 134 to 136)

<p style="text-align: right;">134</p> <p>1 Q. And then at some point in that</p> <p>2 process, you would generate a list of the</p> <p>3 products that fit the code; is that true?</p> <p>4 A. Yes.</p> <p>5 Q. And if you turn to Exhibit 262 on Page</p> <p>6 CIGNA 0102, is that a representation of what such</p> <p>7 a printout would look like?</p> <p>8 A. Yes.</p> <p>9 MR. FAUCI: I have no further</p> <p>10 questions.</p> <p>11 EXAMINATION</p> <p>12 BY MR. GORTNER:</p> <p>13 Q. Just a quick follow-up since we're on</p> <p>14 this exhibit. If you go to CIGNA 0110, is that</p> <p>15 similar to the page that Mr. Fauci was just</p> <p>16 asking you about, that same page would be</p> <p>17 generated when you enter ipratropium bromide and</p> <p>18 go through those steps?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. So by entering ipratropium into</p> <p>21 the search screen on Red Book CD-ROM, it would</p> <p>22 include this list of ipratropium bromide products</p>	<p style="text-align: right;">136</p> <p>1 REPORTER'S CERTIFICATE</p> <p>2 I certify that the witness in the</p> <p>3 foregoing deposition, CAROLYN HELTON, was by me</p> <p>4 duly sworn to testify in the within entitled</p> <p>5 cause; that the said deposition was taken at the</p> <p>6 time and place therein named; that the testimony</p> <p>7 of said witness was reported by me, a Shorthand</p> <p>8 Reporter and Notary Public of the State of</p> <p>9 Tennessee authorized to administer oaths and</p> <p>10 affirmations, and said testimony, pages 1 through</p> <p>11 117 was thereafter transcribed to typewriting.</p> <p>12 I further certify that I am not of</p> <p>13 counsel or attorney for either or any of the</p> <p>14 parties to said deposition, nor in any way</p> <p>15 interested in the outcome of the cause named in</p> <p>16 said deposition.</p> <p>17 IN WITNESS WHEREOF, I have hereunto</p> <p>18 set my hand the 19th day of October, 2009.</p> <p>19</p> <p>20 _____</p> <p>21 Elisabeth A. Miller, RPR, RMR, CRR</p> <p>22 My commission expires: 3/11/2011</p>
<p style="text-align: right;">135</p> <p>1 at that particular point in time?</p> <p>2 A. Yes.</p> <p>3 MR. GORTNER: No further questions on</p> <p>4 my end.</p> <p>5 MR. FAUCI: Thank you very much for</p> <p>6 your time, Ms. Helton.</p> <p>7 THE VIDEOGRAPHER: This concludes the</p> <p>8 deposition of Carolyn Helton, Volume 1. Number</p> <p>9 of tapes used was two. Going off the record,</p> <p>10 time is 11:52.</p> <p>11 (Proceedings adjourned at 11:52 a.m.)</p> <p>12 FURTHER DEPONENT SAITH NOT.</p> <p>13</p> <p>14 _____</p> <p>15 SIGNATURE OF THE WITNESS</p> <p>16</p> <p>17 Subscribed and sworn to and before me</p> <p>18 this _____ day of _____, 20____.</p> <p>19</p> <p>20</p> <p>21 _____</p> <p>22 Notary Public</p>	

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30(b)1 and 30(b)6 Deposition of Helton, Carolyn

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